**[Human Subjects Regulations](http://ra2.haifa.ac.il/index.php/en/policy-a-compliance-4/human-subjects-regulations.html)**

**Procedures governing the use of Human Participants in Research**

**Ethics Committee Regulations for Research Work involving Human Participants**

**Introduction**

Human society uses research to develop human knowledge toward objectives of extreme importance. The academic community invests tremendous efforts in promoting research. The need to consider the ethical aspects of research has been recognized worldwide. As research involving human participants has expanded and its methods have become more diverse, flaws and ethical problems have emerged in the planning and implementing of some research projects. Countries as well as international, national and professional organizations and institutions have recognized the need to formulate regulations and to institute procedures to increase awareness and minimize damage and errors. These are not intended to hinder research or to place unnecessary difficulties in its way but rather to reinforce the basis of the research.

**Research –**In these regulations, the term "research" encompasses all the activities involved in it: observation, questionnaires, surveys, case studies for examination and the like. The term "research" also includes any form in which the research material is preserved and published.

**Sphere of influence –**In these regulations, "sphere of influence" refers to that area of affinity/belonging containing the research participants' sources of spiritual, emotional and material existence. The language of these regulations refers to preserving the freedom and integrity of the participant in this sphere of direct and indirect influence.

**Damage and risk –**These refer to any and all influences that the participant and/or an individual who is independent of and not connected to the research define as harmful, risky or negative influences, without these being subject to legal proceedings.

**Researcher** [**[1]**](http://ra2.haifa.ac.il/index.php/en/policy-a-compliance/human-subjects-regulations.html#_ftn1)**–**Any individual who carries out research and is affiliated with the University as an employee, member of the academic faculty or research student.

**Research participant –**Any individual who has consented to assist the research through his participation (also referred to as "subject" or "examinee").

**I.              Basic Principles**

This document is based on a number of basic principles that guide the proposed regulations. These basic principles deal with two main points: the research on the one hand and the research participants on the other. The basic principles relating to the research include the objective of academic research to advance human knowledge, processes supporting the research, peer review and criticism, academic integrity, and maintaining transparency as a basis for knowledge. The basic principles regarding research participants (subjects) include preserving participants' human dignity, basic human rights and welfare and protecting them from physical and emotional harm, harm to their dignity and the like.

**Peer review –**The basic academic principle of ethical supervision of research is identical to the principle governing the control over research proposals and publications – the principle of peer review.  This is the source of the notion that every research should undergo preliminary ethical supervision. Similar to other types of review, ethical review depends on professional proximity to the field of the research proposal. Therefore, the faculty or departmental ethics committees should have authority in terms of review and approval. However, they are subject to the basic procedures and principles that appear in this document.

**Academic integrity –**Researchers must maintain academic integrity in anything related to preserving the rights of their research colleagues, the rights of the research participants, and their own rights as researchers to academic freedom in anything related to the way in which the research is conducted and to the publication of the knowledge deriving from it.

**Human rights** – In accordance with the basic principles of human rights, research must not discriminate against any individual (based upon religion, gender, age, ethnic origins, socioeconomic status and the like). Researchers are bound by the ethical obligation to represent the population of their research without any discrimination whatsoever, so that the research results will be relevant to diverse population groups and will benefit humanity as a whole. Nevertheless, it is obvious that in some research studies and circumstances this principle does not apply, due to the nature of the research or to methodological considerations.

**Respecting, benefitting and protecting research participants –**Research involving human participants is based on the understanding that the objective of advancing human knowledge is to promote the welfare of human beings in general, and of the research participants in particular, and to protect them from any undesirable and unnecessary harm.

**The research participant is not an instrument –**In accordance with the above, the human participant is not himself the objective and should not be made the instrument of realizing any objective whatsoever. For the purposes of these research procedures, an individual who has given his consent to assist in the research through his participation is not considered a research instrument.

**Free consent –**Any activity that appears to contradict these principles can be undertaken on the explicit condition that the individual has given his free consent, devoid of any overt or covert coercion, attractive benefits and the like. If the free consent of the individual about to participate in a research activity that contradicts one of these principles cannot be obtained and/or is not admissible, as in the case of a minor, someone who is ill, someone who is far away from the venue of the activity, etc., he is entitled to strictly supervised guardianship (after authorization by the Committee).

**Validity of rights –**The rights of an individual extend beyond the time and place of his current location. Therefore, his confidence vis-à-vis the fear of losing his liberty, his equal rights, etc. is also valid in the future, as well as in places where he personally is not present but are associated with him in practice or potentially.[[2]](http://ra2.haifa.ac.il/index.php/en/policy-a-compliance/human-subjects-regulations.html#_ftn2)

**II.           Implementation of the Principles in Research Relations**

**A.    Informed Consent of Research Participants**

**Informed consent –**Informed consent insures that the research participant (subject) has the ability to agree, is capable of making a decision out of genuine free choice without any overt or covert coercion, and with full knowledge of the nature of said consent. The researcher is obligated to explain to the research participant or to his representative (see below) the characteristics of the research: its objective, its methods, its potential impact, including the advantages and disadvantages for the participant. The ways in which the research is preserved and publicized and the chain of responsibility, the institutions conducting the research, the sources of funding, etc. will be placed at the disposal of the research participant should he so request.

**Consent by a guardian –**If a research participant is not capable of giving consent or of exercising judgment, the consent of the participant's legal guardian must be obtained. The researcher must obtain the consent of every participant capable of expressing consent, even if this participant has a legal guardian who has expressed his consent.

**Transparency –** All applications to the Ethics Committee and their supporting documents including the Committee's deliberations on the matter, and specifically including the research protocols, Committee decisions and deliberations involved in every proposal, will be stored in archives which are under the responsibility of and accessible to the Dean of Research/Vice President for Research, and will be made available to any involved party.

**Minors, Wards and Dependents –** With respect to minors, wards, dependent individuals who are ill or in a condition where they are not properly aware of the significance of the details outlined above, the researcher is obligated to obtain permission from the legal guardian of the participant, and in the case of participants able to understand what is being done with them, the researcher must also obtain the consent of the participants.

**The right not to participate –** The researcher is obligated to explain to the research participant that he is entitled, for any reason whatsoever, to change his mind about his initial consent to participate in the research, up to the stage where data collection has been completed, without this lack of consent or withdrawal from the research harming him in any way.

**Lack of dependence –**The research participant will not be dependent upon the individual carrying out the research with respect to material dependence, disciplinary-authoritarian dependence or emotional dependence.

**Lack of coercion –**In situations in which a third party limits the freedom of choice of the subject, participation in the research will not constitute a condition for granting benefits or withholding rights by a third party (for example, soldiers, prisoners, inmates or wards of institutions, employees of a company, students).

**B.     Protection of and Benefits to Participants**

**Protecting participants –**In order to protect the safety of the participants, the Committee can discontinue the research at any stage, remove participants from the research, or take any other step it deems necessary.

**Preventing harm to participants –** No research study can be carried out that endangers a participant or is likely to cause him harm without balancing this against results likely to benefit him considerably, even if he was promised or received monetary or other compensation for his participation.

**Preventing humiliation and discrimination –** Research studies are not to be carried out that at any stage risk causing humiliation, discrimination of any type, and the like, even if the participant or his representative have given consent to this.

**Protecting participants from exposure –** No research proposal will be approved that permits the exposure of participants' personal details in any way that is likely to harm them in the future, and in particular exposure to the party that has funded or ordered the research, without the independent approval of the research participants.

**Sensitive population groups and harm in institutional settings –** In the case of sensitive or vulnerable population groups, in institutional settings or under the direct responsibility of a government or public body, the researcher is responsible for obtaining the approval of the authority/institution responsible for the members of this particular population group (e.g., the Ministry of Education, the Prison Service, the Ministry of Defense, etc.). This approval, and/or the approval of the Helsinki Committee, does not constitute a substitute for the approval of the University Committee charged with authorizing the research. For the sake of avoiding duplication, such approval can be presented for examination to the Committee, which will examine whether other considerations are needed to grant University approval.

**Benefit to participants lacking the ability to consent[[3]](http://ra2.haifa.ac.il/index.php/en/policy-a-compliance/human-subjects-regulations.html" \l "_ftn3" \o ") –** To ensure that a participant who does not have the ability to consent will not be taken advantage of or abused, the researchers must make sure that the research will be of direct benefit to the participant, either through its results or by some sort of compensation.

**Guardian's presence during the research –** Research studies with participants who are dependents, wards or minors should be carried out with the direct or indirect presence of the guardians or appropriate adults. If their presence is not desirable from the perspective of the research, the researcher must invite a colleague to provide heightened protection of the participant's rights.

**Population groups that are not Israeli –**In the case of research studies using population groups that are not Israeli or that take place outside the borders of Israel and use participants that are not citizens of Israel, either the rules and regulations applicable in the country where the research takes place or those set out in these procedures will apply, **whichever are the most stringent.**The research study will comply with the rules of ethics applicable to research carried out in Israel, regardless of nationality.

**C.    The use of distortion or the concealing of essential information from the participants**

**Concealing and distorting information as part of the research –**Research studies whose very nature is related to the factor of the research participant's lack of knowledge, to the factor of surprise and secrecy, and/or to distortion must obtain the consent of the Ethics Committee for this concealment or distortion. Researchers should aspire to limiting such concealment or distortion to the extent possible.

**Justifying the use of distortion or concealment –** In principle, researchers do not conduct research studies involving concealment or distortion unless they are convinced that the use of distortion techniques is justified by the scientific, educational or practical value of the research, and that an effective alternative that does not involve distortion is not available. A satisfactory explanation for the necessity of the concealment or the distortion must be submitted to the Ethics Committee.

**Lack of concealment of potential harm to participants –** Researchers will not mislead future participants and will not conceal from them that the research is likely to cause severe physical pain or emotional distress.

**Exposure of distortion or concealment –** Researchers are required to reveal to the research participants and to explain to them any distortion or concealment that constitutes an integral part of the research, as soon as possible from the perspective of the nature of the research, but no later than the end of data collection, and they must allow participants to drop out and to withdraw their data.

**D.    Researchers applying to the Committees**

**Training researchers in research ethics –**Without derogating the applications currently (2010) submitted, every researcher who submits an application to the Ethics Committee regarding research using human participants must complete a training program in the ethics of research using human participants, for example the program offered by the American National Institutes of Health (NIH) or an equivalent course dealing with the protection of human participants, prior to submitting the research proposal to the Research Authority. Certificates of completion will be submitted to the Research Authority and transferred to the archives.

**Researcher's obligations in the research planning stage**

1. **Acceptability of the study from the ethical perspective – In the stage of planning research studies involving human participants, it is the obligation of the researcher to carefully assess the acceptability of the study with respect to principles of ethics (see appendix).**
2. **Responsibility for conducting the research study –**The researcher is responsible for carrying out the research, and for its content and methodology. The researcher is obligated to explain the ethical principles involved in the research to his partners and assistants.

**Research proposals submitted by students –**The guiding principle is that every research study involving human participants must undergo peer review. Student research studies are no exception to this rule.

1. **B.A. –**In the case of research studies conducted by undergraduate students and supervised by researchers from the academic faculty of the University, the Committee can consider approving comprehensive models for student research, such as research seminars and the like, because these usually make use of tools and methods that repeat themselves, for example, the use of certain types of computerized tests, approved questionnaires, fixed categories of participants, etc. The research supervisors must be responsible for updating and for carrying out new examinations when changes are made in a model approved in the past.
2. **M.A./Doctorate –** In the case of research conducted by graduate students (M.A. and doctorate), these studies are exclusive to the student and his research objective, and therefore the entire research proposal of a student for a higher degree must be examined.

**Applications by colleagues who are not members of the University faculty –**The Ethics committees will consider approving applications from colleagues abroad (or applications from public, commercial or collegial organizations in Israel as well) seeking to conduct research in Israel, even if the said research is not related to the University, as a collegial service, in a way that is expected of other institutions to act toward researchers from the University.

**III.        Procedures[[4]](http://ra2.haifa.ac.il/index.php/en/policy-a-compliance/human-subjects-regulations.html" \l "_ftn4" \o ")**

**Committees**

**The committees have three objectives:**

1. To promote education for and awareness of ethical research using human beings according to accepted standards.
2. To review research proposals submitted to them and to consider whether these proposals meet the standards for ethical research, and to suggest corrections and to ask for additional information which may improve the ethical foundations of the research.
3. To approve research proposals that the Committee believes meet the current requirements for ethical research.

**Establishing Ethics Committees –**The University Ethics Committee under the auspices of the Research Authority (the Supreme Ethics Committee) and its members are appointed by the Rector / Vice President for Research. Other committees will be established in accordance with the procedures of the faculty or department funding them.

**Principle of committee sovereignty**

Structure of the committees – It is recommended that each committee include 5-8 members from different backgrounds in order to promote comprehensive and sufficient control over the research activities, which are usually carried out at the University. At least one member of the committee must be conversant with the scientific aspects of the proposed research. One member of the committee must be from outside the University and must not have any family relationship or other interests in the University apart from ethical supervision of research studies involving human participants. Moreover, it is also recommended that the minimum number of participants in a plenum discussion be 2-3 members, while for a discussion of proposals in an expedited fast track process[[5]](http://ra2.haifa.ac.il/index.php/en/policy-a-compliance/human-subjects-regulations.html" \l "_ftn5" \o ") two members are sufficient. The institutional review board can, according to its decision, ask individuals with specific expertise to help examine topics that require understanding and expertise beyond that of the members of the committee.[[6]](http://ra2.haifa.ac.il/index.php/en/policy-a-compliance/human-subjects-regulations.html#_ftn6) These individuals do not have voting rights on the committee.[[7]](http://ra2.haifa.ac.il/index.php/en/policy-a-compliance/human-subjects-regulations.html#_ftn7)

**University Committee –**The Committee will review research proposals submitted to it. The Committee of the Research Authority will serve as the supreme committee handling the formulation of University policies on matters of ethics, will promote awareness of and education on research ethics at the University and in cooperation with other institutions of higher education, and will advise the faculty ethics committees on the ethical matters they submit to it, will approve procedures determining the faculty ethics committees, and will be involved in coordinating and administering the network of ethics committees, without derogating the sovereignty of the faculty committees to make decisions in the field of their authority and their professional specialization, and will hold meetings of the chairs and members of these committees from time to time.

The Committee seeks to obtain feedback and conduct a dialogue with members from within and outside the University community, with the intention of improving the conditions for research using human participants.

This Committee will serve as a committee of ongoing formulation that will propose and receive proposals for changes in these regulations according to new needs that arise.

**Faculty and departmental committees –**Ethics committees will be established in every faculty that conducts research using human participants. The decision to establish additional committees (for example, in departments or schools) will be made in conjunction with the University Ethics Committee. The existence of a number of large institutional committees operating in parallel will facilitate division of the work load as follows: a) among the committees; b) among the members of the committee; c) because committees sometimes review research studies submitted by members of the committee, who are prohibited from taking part in the deliberations. A large committee that operates in a cyclic manner in dividing the work load is capable of reviewing research proposals quickly and efficiently. The committees will review the research proposals submitted to them and will promote awareness of and education for research education in their faculty and department, and in cooperation with the University Committee, at universities in the United States. These jobs are defined as salaried positions.

**Training members of the committee for ethics in research involving human participants** – Every member of the committee for ethics in research involving human participants will complete an initial training program, as well as refresher courses to be approved or created by the institutional Ethics Committee. The members of the committee will be required to take a refresher course once every five years.

**Documentation requirements –**Every committee will be required to make sure to submit organized documentation such that the information is preserved for seven years in the committee archives managed by the Research Authority.

This documentation will include the following:

1. The members of the committee and the date each member was appointed.
2. The committee's working regulations and information on its decision-making processes, including recording the dates an application was submitted for approval, the details of the deliberations and the decision made, and the date the researcher was notified of the results of his application.
3. The application and relevant material.
4. Notifications to the researchers.

**A.    Procedure for submitting an application**

Every researcher must be familiar with the University's requirements with respect to research involving human participants, located on the websites of the Research Authority and the committees, as well as the accepted international guidelines on this matter. The American Psychological Association (APA) has issued a series of rules and procedures to ensure ethical research, which can be found on the APA website. In addition, many universities and academic organizations publish their own guidelines for carrying out research involving human participants.

**Selecting the committee for submitting the proposal –** Every research study at the University of Haifa involving human participants must be examined by a committee for ethics in research involving human participants. A researcher can select the committee to which he submits his proposal for approval.

The proposal forms (located on the committee websites) and additional documents are filled out and submitted to the committee electronically (not in picture format and not as scanned documents, to enable the committee members to work on the submitted materials using a word processor). There is no need for submitting a signed hard copy. It is sufficient to submit the proposal by e-mail or by means of entering an electronic portal at the University that requires the researcher to identify himself.

In accordance with the committee's request, all material required for reviewing the proposal must be submitted to the committee, including the complete research proposal, agreements with sources of funding, etc.

The committee can also review the methodology of a proposal in order to make sure it is appropriate to the research expectations in weighing its value against its ethical cost.

**B.     Review process**

At the time of their submission, applications are sent electronically to the members of the committee. Most of the committee's work can take place by means of electronic mail. The committee members can ask for clarifications from the researchers, ask for changes in the proposal, or ask to convene the committee to discuss the proposal. The researcher can be asked to join the committee's meetings to discuss the research proposal, and to clarify and explain matters related to the proposal. All of these possibilities are available to every member of the committee, even though a clear hierarchy does exist:  If a member of the committee asks that the committee be convened, this request takes priority over a vote by electronic means. Low risk proposals can be approved in an expedited fast track process unless a member of the committee should object to this.

Decisions will be passed by a majority of votes. The chairman has the right to determine the decision in the event of a tie.

Transfer of the proposals to the members of the committee should include the following points:

1. Whether the proposal is acceptable as a "fast track" proposal.
2. Whether the members of the committee are interested in convening to discuss this proposal.
3. Whether the committee member approves the proposal.
4. Committee members may propose approval dependent upon minor changes.
5. Whether the committee member has any advice for the researcher for improving the research proposal (whether or not the proposal is approved).

Committee Chair:

1. The committee chair can determine a reasonable target date for responses from the committee members, and as a default can suggest a minimum number of votes required for approval, unless one of the committee members objects.
2. The committee may propose approval conditional upon minor changes to the proposals. If these changes are not acceptable to the researcher, the approval is revoked.
3. The chair of the committee sends the approval letter to the researcher, with a copy to the Research Authority, and attaches the approved proposal for filing in the Research Authority archives.

Then the Research Authority:

1. Files the proposal and the supplementary materials, as approved.
2. Issues an approval number directly to the researcher, with a copy to the committee.

**Fast Track procedure –**A research proposal that meets the following conditions is exempt from a detailed application and is discussed in an expedited fast track procedure: an anonymous study that does not enable identification of the participants and does not include fraud or deception, is in no way intrusive vis-à-vis the personal life of the individual, does not include any danger or minor risks, and participation in the study indicates consent to significant participation. A fast track procedure can be suggested by the researcher or by any member of the committee. Any committee member has the right to veto the fast track procedure within two days of submission of the application. In a fast track procedure, the proposal will be read by two committee members only.

**C.    Approved proposals**

The researcher receives a letter of approval from the committee to which he applied and an approval number from the Research Authority. All materials pertinent to the proposal will be filed by the Research Authority, because the members of the committee change frequently, protocols for preserving data change, etc.

Letters of approval will include the following:

1. Proposal title
2. Declaration of approval
3. Any demand for stipulated changes.

                              i.        Clarification that the documents changed in accordance with the above must be sent to the Research Authority for filing.

                             ii.        Clarification that if the stipulations are not acceptable to the researcher, the approval is null and void and the proposal must be reexamined.

1. Any non-obligatory proposal or recommendations that the committee members issue from time to time.
2. A declaration that the approval is not valid if the research deviates from the stipulations of the approval and the revised proposal. Any significant change during the course of the research must be sent to the Committee for its examination and approval.
3. A request to include the approval number in all publications to the participants, in reports, articles and other publications, etc. For example: Approval Number XXXXX, Committee for Ethics in Research Involving Human Participants at the University of Haifa.
4. Acknowledgment of the researcher's cooperation and wishes for a successful research study.
5. The approval letter must include a statement that it is the researcher's obligation to ensure that he has received the approval number from the Research Authority, for without this number it will be difficult to find the proposal and the approval after months and years have passed, if needed, for example in the case of translation into English, new research cooperation, research funds, publications, etc.

**D.    Approval Validity, Incidents and Changes during the Course of the Research**

**Validity of Committee approval** – Approvals issued by the committees will be valid for a period of 4 years, unless the Committee decides otherwise or if the funding organization demands some other cycle of reevaluation by the Committee. After the approval period has ended, if necessary the researchers will submit a request for renewal of the Committee's approval.

**Changes in the proposal –**In the event of changes in the implementation of the research, all such changes must be submitted to the Committee for review and approval before they are implemented. This same principle applies to everything related to changes in the explanation form given to the research participants or in the informed consent form to be signed by the research participants. During the review, the members of the committee have the right to reevaluate the entire proposal, and not only the changes. This principle is intended to ensure that the research is congruent with the values, criteria, legislation and regulations, which may have changed or developed since the time of the original proposal.

**Changes in the group of principal investigators –**When a principal investigator retires, leaves the research study or changes in any way whatsoever, the researchers must submit a request to the Ethics Committee to make a change in the group of researchers. The principal investigator is responsible for informing the Ethics Committee of his change in status and for arranging another principal investigator in his place.

**Detrimental incidents –**Incidents that are potentially detrimental and threatening to research ethics occurring during the course of the research must be reported to the Ethics Committee by the researcher immediately after they occur or upon his becoming aware of them. The Ethics Committee will review the incident and determine whether any changes in the research are required, and will document its response to the incident.

**Researcher responsibility –** The researcher is responsible for conducting ethical research as well as for fulfilling the conditions of the approval granted. The approval does not exempt the researcher from this responsibility. Ethical approval is a service granted to the researcher by his peers and is identical to the principles regarding review of research proposals and papers – the principle of peer review, and as in all these cases the final responsibility for the researcher's work and for the ethics of his research falls upon him.

**Resources**

In order to implement the principles and procedures outlined in this document, resources must be allocated to put them into effect. These resources include administrative positions, allocation of suitable computer resources, and compensation for the members of the academic faculty serving on the committees. The committees existing today work on a volunteer basis, and the resources allocated voluntarily by the faculty members, the faculties and departments, and the Research Authority are overburdened and on the verge of collapse, a situation likely to worsen upon implementation of this document.

[[1]](http://ra2.haifa.ac.il/index.php/en/policy-a-compliance/human-subjects-regulations.html#_ftnref1) The language throughout this document is intended to refer equally to men and women researchers, research participants, etc.

[[2]](http://ra2.haifa.ac.il/index.php/en/policy-a-compliance/human-subjects-regulations.html#_ftnref2) For example, the effects of social status or long-term personal, social or health implications.

[[3]](http://ra2.haifa.ac.il/index.php/en/policy-a-compliance/human-subjects-regulations.html#_ftnref3) The advancement of research and knowledge is valuable, and hence the participant's contribution to the research is a benefit. This is not comprehensible to participants who lack the ability to consent.

[[4]](http://ra2.haifa.ac.il/index.php/en/policy-a-compliance/human-subjects-regulations.html#_ftnref4) It is proposed that the Senate certify that this part is subject to changes according to need and with the approval of the Vice President of Research upon the recommendation of the Executive Committee.

[[5]](http://ra2.haifa.ac.il/index.php/en/policy-a-compliance/human-subjects-regulations.html#_ftnref5) See below.

[[6]](http://ra2.haifa.ac.il/index.php/en/policy-a-compliance/human-subjects-regulations.html#_ftnref6) Occasionally we need supportive experts and advocates from the fields of law or medicine, or specialists in children, soldiers, older adults, mentally ill individuals, prisoners, etc., according to the types of problems we encounter and that require special expertise, rather than relying only upon experts who happen to be on the committee. When necessary, it is appropriate to have access to such a team, whether within the University or from the outside.

[[7]](http://ra2.haifa.ac.il/index.php/en/policy-a-compliance/human-subjects-regulations.html#_ftnref7) Recommendations of the OHRP – United States Office for Human Research Protections.