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Guideline name:

Regulations on Conflict of Interest in Research

1. General:

Tel Aviv University Researchers will perform their research in an impartial manner and will act in their function using purely professional considerations. Tel Aviv University Researchers will disclose any interest they may have, or appear to have, to bias the research or unduly influence decisions regarding the conduct of the research. Such disclosure allows for taking measures to ensure that the research is performed in an impartial manner and independently and professionally.

"Research" means research conducted at Tel Aviv University, in subsidiaries and/or external institutes and/or on behalf of Tel Aviv University and/or that Tel Aviv University is supervising.

"Tel Aviv University Researchers" means employees, pensioners, visitors and students or post-doctoral fellows involved in the research (including within their degree studies), planning the research, the submission of research proposals for funding, in management or reporting on the research, or in the decisions in relation to its commercialization, and also any person utilizing University resources and/or involved in research with any of the persons enumerated above.

It is clarified that external entities purchasing laboratory services from the equipment centers at the University are not subject to these Regulations and are not partners in the University research.

Reference in these Regulations to the masculine form includes the feminine form by implication, and reference to the singular includes the plural by implication, and vice versa.

2. What is considered a conflict of interest in research?

A conflict of interest in research exists where there is concern that an extraneous consideration will bias the independent and professional judgment required in research. A conflict of interest shall include an actual or potential conflict of interest.

For the purpose of examining the existence of a conflict of interest, it is sufficient that as regards the objective data and on the basis of reasonable considerations based on life experience and commonsense, a suspected conflict of interest is likely to arise. The researcher's personal feeling with regards to the extent of the effect of the extraneous considerations is irrelevant.

Actual or potential conflict of interest:

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<u>Actual conflict of interest</u> is a situation in which a real likelihood <u>actually exists</u> that the independent and professional judgment required for academic research will be biased by an irrelevant consideration.

<u>Potential conflict of interest</u> is a situation in which it seems possible in the course of the research that the researcher's independent and professional judgment will be biased, or a situation that is <u>likely to develop</u> into an actual conflict of interest.

An "extraneous consideration" may be of any kind – personal, professional, financial, commercial or any other matter. It may be of the researcher himself, of members of his immediate family, of his close friends, of the financing entities or of any other person or entity.

Characteristic, although not exhaustive, situations in which a conflict of interest arises are the following:

- 2.1 When the researcher (or members of his immediate family, his close friends, his students or any other person or entity to which he is affiliated) is linked to the entity funding the research, in such a way that will enable him to benefit from a direct or indirect monetary gain from the research, there is an actual conflict of interest, requiring disclosure and management (see section 4 below). Also, when there is no actual likelihood of monetary gain, there is likely to be a potential conflict of interest, requiring disclosure and management (and also when one of the persons mentioned above considers contacting the financing entity).
- 2.2 When the entity funding the research has a financial interest or other non-academic interest in the research results, such as the commercialization thereof, there is not always an actual conflict of interest, but there is likely to be a potential conflict of interest requiring disclosure and management.
- 2.3 When the financing entity or Tel Aviv University Researcher (or members of his immediate family, close friends or his students) or any other entity with which the Tel Aviv University Researcher is affiliated or in which the Tel Aviv University Researcher has an interest, are interested in or are likely to benefit from the delay in publication, from a partial or misleading publication or from the non-publication of the research results, there is an actual conflict of interest requiring disclosure and management

For the avoidance of doubt, delay, partial publication or non-publication of the research results for the professional-academic considerations of the Tel Aviv University Researcher will not constitute a conflict of interest *per se*.

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- 2.4 When personal profit or personal or significant professional benefit (exceeding regular professional promotion) are dependent on the research results, there is an actual conflict of interest requiring disclosure and management.
- 2.5 When a person involved in the research has a personal interest that is likely to be affected by performance of the research or its results.

"Personal interest" includes a personal interest of a relative of such person or an interest of an entity managed by the researcher or his relative or in which they are members or in charge of, or an interest of an entity in which each of them holds part of its share capital, a right to obtain profits, a right to appoint a director or a voting right. For the avoidance of doubt, it is clarified that minimal holdings in corporations whose shares are listed for public trading on the stock exchange, directly or indirectly, within securities portfolios and/or trust or pension funds, as is customary with a large number of ordinary people, will not be deemed a personal interest.

3. General Obligations:

- 3.1 The independent, professional and impartial judgment required from an academic researcher will not be biased by extraneous considerations.
- 3.2 Tel Aviv University Researchers will uphold the obligations of disclosure set forth in these Regulations and will comply with the decisions of the Conflict of Interest Committee.

4. Duties of disclosure:

4.1 **Disclosure at the time of submission of a research funding application:**

A conflict of interest declaration from the principal investigator will be included in each research proposal form submitted to the Research Authority on the absence of any conflict of interest, as set forth in the form, relating to all the Tel Aviv University Researchers involved in the research.

The principal investigator will ensure that all those operating in cooperation with him and/or on his behalf in the research signed and/or will each sign (upon commencement of his involvement in the research) a declaration according to the form attached as **Appendix A**, and he will keep their declarations for documentation and control purposes for at least two years after the conclusion of the research.

Any actual or potential conflict of interest arising in the course of the research will be immediately reported to the Conflict of Interest Committee.

4.2 **Disclosure by a doctoral student:**

Conflict of interest declarations of a student and his PhD supervisor will be attached to the application for acceptance to studies and also the application for approval of the research proposal, submitted to the Research Students Office, with regard to the proposed research. The student and his PhD supervisor shall declare their understanding of the rules and undertake to act in accordance with such rules. The wording of the declarations is attached as **Appendix B**.

If the departmental committee deliberating the acceptance of a student for studies or the application for approval of the research proposal, finds there is concern as to a conflict of interest, the University Committee for Research Students will decide the matter. This Committee will also have authority to deliberate on situations where concern arises as to a conflict of interest in the course of the research student's studies.

4.3 Ad hoc declarations:

Tel Aviv University Researchers will disclose to the Conflict of Interest Committee, at their initiative, any actual or potential conflict of interest arising in the course of their research not disclosed in the research funding application, or which has changed since it was disclosed. The conflict of interest will be reported immediately when it arises.

5. Consultation:

Tel Aviv University Researchers may consult with the Conflict of Interest Committee to examine whether their situation constitutes an actual or potential conflict of interest and how to avoid or manage such a situation.

6. Documentation:

Declarations of a principal investigator discussed in section 4.1 and also declarations in section 4.3 above, requests to consult with the Committee and documentation of the work of the Conflict of Interest Committee will be filed with the Research Authority, and any authority competent to handle conflict of interest matters and violations of the University Rules will have authority to review them.

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The declarations stated in section 4.2 will be filed in the student's personal file in the office of the department in which the student is studying.

7. The Conflict of Interest Committee:

7.1 **Composition of the Committee:**

The Committee is composed of 7 members: the Vice President for Research and Development will serve as Committee Chairperson, 4 members at the rank of full professor, who represent the various fields of research at the University, a public figure and the Director of the Research Authority. The Director of the Research Authority will serve as Committee coordinator. A representative of "Ramot" will be invited to the Committee who will serve as an observer (without a voting right).

- 7.2 The Rector will appoint those members of the Committee not appointed by virtue of their position, including a public figure. The appointment will be for three years, and it will be possible to extend this period for an additional three years. The appointment will require the approval of the Senate Steering Committee.
- 7.3 No more than 30% of the members of the Committee will be replaced at one time, to ensure the continuity of the Committee's work.
- 7.4 The number of members required for a quorum of the Committee is 5 members.

8. Activities of the Conflict of Interest Committee:

- 8.1 In any case brought to the attention of the Conflict of Interest Committee, either by the Research Authority (following applications for funding of researchers), either by disclosure of a Tel Aviv University Researcher or upon consultation by a Tel Aviv University Researcher with the Committee, the Committee will hear the matter and decide how to act.
- 8.2 The Committee may decide as follows:
 - (1) The situation does not require any handling whatsoever.
 - (2) The specific Tel Aviv University Researcher must disclose the conflict of interest to designated persons or entities, as the Committee sees fit.
 - (3) The research program must be changed in a manner that will prevent a conflict of interest or that will enable its management.

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- (4) To appoint a person to independently supervise the research planning, management or reporting.
- (5) The Tel Aviv University Researcher must divest himself of the financial interest in the entity funding the research or in the entity having a non-academic interest in the research results.
- (6) The Tel Aviv University Researcher must sever ties with the person or entity with respect to which the conflict of interest arose.
- (7) The Tel Aviv University Researcher must be disqualified from participation in all or part of the research.
- (8) Any other measure must be taken which is deemed appropriate in order to avoid or manage the conflict of interest.
- (9) Disciplinary action should be recommended to the Rector.
- 8.3 Before it decides whether there is an actual or potential conflict of interest requiring management, and the desirable measures to manage it, the Committee will hear the position of the Tel Aviv University Researchers involved as to the situation in question and suitable measures to manage it, if they so desire. In special cases the Tel Aviv University Researchers will be allowed to present before the Committee the written or oral positions of others.
- 8.4 When deciding whether there is an actual or potential conflict of interest requiring management, and the desirable measures to manage it, and if these rules do not provide other explicit arrangements, the Committee will be guided by accepted standards on such matter at academic institutions in Israel and abroad.
- 8.5 All deliberations of the Committee, including those in which the Tel Aviv University Researcher participates, excluding previous clarifications and exchanges of ideas, will be made face-to-face, and not in writing or by email. However, a Tel Aviv University Researcher may present his position also in writing if he so desires. A record of the content of the deliberations will be kept.
- 8.6 All decisions of the Committee will be given in writing. The decisions and documentation of the Committee deliberations and of the decision process will be made available to the members of the Committee and the researcher involved, at their request.

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- 8.7 When deciding whether there is an actual or potential conflict of interest requiring management and what measures are desirable for its management, the Committee may adopt interim decisions as it deems fit, such as the suspension of the researcher from involvement in the research, disclosure of the situation to the financing entity, freezing the research funds etc., until a final decision is reached. This authority will not be exercised without the researcher having being given an opportunity to be heard, and no measure will be taken that will be more detrimental than necessary to the progress of the Reaserch or the relationship between the researcher and the financing entity.
- 8.8 An appeal on the decisions of the Committee will be heard before the Committee together with two members: one will be the University Rector and the other will be the Chairperson of the University Ethics Committee. The minimum number of members required for a quorum of the plenum is 7 members holding a voting right, including the Chairperson of the Committee and the two additional members.
- 8.9 Where a complaint has been submitted to the Rector on breach of the provisions of these Regulations, he will transfer the examination of the complaint to the Committee which will act for the examination of such complaint and will submit its recommendations to him.
- 8.10 The decisions of the Conflict of Interest Committee are binding on Tel Aviv University Researchers.

9. Additional Rules

- 9.1 Information passed on by a Tel Aviv University Researcher to the Conflict of Interest Committee about the research will be kept privileged.
- 9.2 The existence of University rules concerned with other matters relating to the commercialization of the research, such as rules on the relationship between an academic employee and a business entity and rules concerned with exploitation of inventions and patents does not exempt a Tel Aviv University Researcher from his obligations under these Regulations.
- 9.3 In addition to the foregoing in this regulation, Tel Aviv University Researchers will comply with the requirements of the entities funding their research, in relation to a conflict of interest and its disclosure (such as the requirements of the US Government).

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This version is an English translation of the Regulation published in Hebrew at TAU's web-site. In the event of contradiction between this English version of the Regulation and the Hebrew version, the latter will prevail.

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Appendix A

Tel Aviv University

Declaration of Participant in Research Concerning:

Proper Conduct in Research and Conflict of Interest

Name:	Position:
Telephone:	Email:
Principal investigator:	Telephone:
Email:	

Name of research to which the declaration refers:

I hereby declare by my signature as follows: (please mark X on the sections to which your declaration refers).

I have read the "Regulations on Proper Conduct in Research" and the "Regulations on Conflict of Interest in Research" and understood the obligations applying to me on account thereof.

The principal investigator brought to my attention the rules on conflict of interest in research and I confirm that they are clear and understood by me.

I am not and do not expect to be in a situation of any conflict of interest in connection with the research.

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I am and/or I expect to	be in a situation of	a conflict of interest, as	set forth below:
Date:		Signature:	

* This declaration will be kept for documentation and control purposes by the principal investigator for at least two years.

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Appendix B

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Research Student Declaration Concerning:

Proper Conduct in Research and Conflict of Interest

Student Name:	Telephone:
Email:	
Name of supervisor:	Telephone:
Email:	

Name of research work to which the declaration refers (if already in existence):

I hereby declare by my signature as follows: (please mark X on the sections to which your declaration refers).

I have read the "Regulations on Proper Conduct in Research" and the "Regulations on Conflict of Interest in Research" and understood the obligations applying to me on account thereof.

The PhD supervisor brought to my attention the rules on conflict of interest in research and I confirm that they are clear and understood by me.

I am not and do not expect to be in a situation of any conflict of interest in connection with the research work.

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 \Box I am and/or I expect to be in a situation of a conflict of interest in connection with the research work, as set forth below:

Date: ______ Signature: _____

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PhD Supervisor Declaration Concerning:

Proper Conduct in Research and Conflict of Interest

I hereby declare by my signature as follows: (please mark X in the sections to which your declaration refers).

I have read the "Regulations on Proper Conduct in Research" and the "Regulations on Conflict of Interest in Research" and understood the obligations applying to me on account thereof.

I brought to the student's attention the rules on conflict of interest in research and he confirmed before me that they are clear and understood by him.

- I am not and do not expect to be in a situation of any conflict of interest in connection with the research work.
- \Box I am and/or I expect to be in a situation of a conflict of interest in connection with the research work, as set forth below:

Name of PhD supervisor: _____

Date: _____ Signature: _____