Research Grants & Projects Office

Problems completing the form?
Call the RGP: 4027, 4048, 3995 or 4005

Human subject/specimen research

Please SCROLL TO THE BOTTOM OF THE WINDOW to certify your agreement to the following terms:

As you have declared that your research will involve human subjects / specimens, Please note:

A. Human subjects research is to be performed in compliance with applicable legislation, as detailed herein.

Local Legislation and Regulations
Human Subjects Research, including the planning, approval, conduct, recording, and reporting thereof, is to be carried out in due compliance with the principles of the Helsinki Declaration, the Public Health Regulations (Clinical Trials in Human Subjects) 1980, the provisions of the Ministry of Health guidelines, and the provisions of the Harmonized Tripartite Guideline for Good Clinical Practice (ICH-GCP E6).

Under the current applicable legislation of the State of Israel, research is approved only upon the approval of the Helsinki Committee, followed by the Hospital Director's approval, further to which the term of validity is determined ("Helsinki Approval").
Some studies also require approval by the Ministry of Health.

Educational research involving collection of data from human subjects is to be carried out in due compliance with the provisions of the guidelines of the Chief Scientist of the Ministry of Education .

US Federal Regulations

Research which is supported by a US federal department or agency is further subject to the Code of Federal Regulations Title 45 Public Welfare Department of Health and Human Services Part 46 Protection of Human Subjects ("HHS Regulations").

HHS Regulations at 45 CFR 46.109(e) require that **continuing review** of research be conducted by an approved Institutional Review Board (IRB) [1] at intervals appropriate to the degree of risk, but **not less than once per year** [2] (regardless of the validity term of the Helsinki Approval).

Compliance requirements

- Research should at all times be conducted under a valid Helsinki / IRB approval.
- Prior to commencing human subjects research, you are requested to provide Dr. Doron Amit, Head, Research Grants and Projects Office, with a copy of a valid Helsinki Approval which covers your current research, and in which you are named as the "initiator" ("yozem") and/or as a "sub-investigator" ("choker mishne").
- If the research is supported by a US federal department or agency you should also ensure that the Helsinki Committee / IRB that has reviewed and approved the research, conducts a continuing review of the research no less than once per year, and provide Dr. Doron Amit with a copy of the continuing review and approval.
- In the absence of a valid Helsinki Approval or if a lapse in IRB continuing review and approval occurs, investigators are requested to stop all human subjects research activities, unless it is in the best interests of the subjects to continue in the research, until IRB review and approval is obtained.
- As per the Vice President's instructions dated May 26, 2009, activation of the project, as well as that of subsequent project periods, shall be conditioned upon full compliance with the above requirements, including, inter alia, the provision of a copy

of a valid Helsinki/IRB approval to Dr. Doron Amit, in addition to all other applicable requirements of the funding agency.
- Failure to comply with applicable regulations may result in termination of the research.

Weizmann Institute Bioethics Committee Review

In order to assist Weizmann Institute scientists in determining which approvals are required, the Institute has established an Institutional Review Board (IRB).

The IRB's role is to evaluate applications for research involving human subjects and/or samples, including work with human stem cells (according to the guidelines published by the US National Academy of Sciences).

Please download the application form from the Forms page of the RGP website, and submit it to the Head of the IRB for review.

Please note that the IRB's review is NOT a substitute for appropriate ethical approval from the collaborating institution and/or source from which relevant samples/data are obtained, when such is required under applicable legislation.

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[1] According to the Israeli legislation currently in force, applications for approval of human subjects research, as defined in the Public Health Regulations (Clinical Trials in Human Subjects) 1980, can only be filed to Helsinki Committees of medical institutions by a Principal Investigator (PI) who is a medical staff member affiliated to such institution.
If your project is supported by US Federal funding, according to the terms of the Institute's Federal Wide Assurance (FWA) for protection of human subjects, you will have to engage with a PI from either Hadassah Medical Organization or Kaplan Medical Center, both medical institutions being designated IRBs for providing IRB review to the Weizmann Institute according to standing agreements. In case you intend to collaborate with a PI affiliated to another medical institution, please contact the Legal Office - Adv. Ilana Eyal (tel. 08-934-3949) for further advice.
[2] GCP Guidelines require same continuing review.

B. You are required to approve the declaration below.

Should you require any assistance with this matter, please feel free to contact Dr. Doron Amit or Dr. Igal Nevo. For assistance in matters of a legal nature please contact the Legal Office - Adv. Ilana Eyal, Tel.: (08) 934-3949.

DECLARATION

Further to my submission of a research grant proposal to

I hereby certify that:

(a) I will be conducting research involving human subjects/specimens, as defined by Israeli and/or US federal regulations;

(b) I have submitted or will submit an application to the Weizmann IRB and will not begin the research before undergoing review by the Committee and obtaining any required approvals (e.g. Helsinki) as relevant to this application.

(c) I have read the document entitled "Human Participant Protections Education for Research Teams", published by the US DHHS NIH, Nov. 2002;

(d) I am aware that I, as well as any personnel in my laboratory that will be involved with said research, must complete a priori a relevant approved training course. Hence, my key personnel as well as myself have completed or will complete the course provided for this purpose by the NIH at: http://phrp.nihtraining.com/users/login.php

(RGP comment: this online training session should take no more than 2 hours to complete)

or, alternatively, will obtain similar US federal agency approved training elsewhere;

(e) I am aware of the fact that with regard to research which by applicable legislation requires Helsinki/IRB approval:

- According to the Israeli legislation currently in force, human subjects research as defined in the Public Health Regulations (Clinical Trials in Human Subjects) 1980, can only be approved by Helsinki Committees of medical institutions for a principal investigator who is a medical staff member affiliated to such institution, and that my status on such applications can be of an initiator ("yozem") and/or a sub-investigator ("choker mishne").
- In case my research is supported by a US federal department or agency, according to the terms of the Weizmann Institute's Federal Wide Assurance (FWA) for protection of human subjects, I will have to engage with a PI from either Hadassah Medical Organization or Kaplan Medical Center for providing IRB review of the research protocol. In case I will collaborate with a PI affiliated to another medical institution, I will seek further advice from the Legal Office - Adv. Ilana Eyal, tel. (08) 934-3949.

(f) I am aware of the Institute's regulations regarding the execution of human subjects research and I certify that I abide by and will continue to abide by all the requirements and duties which these regulations entail.

I certify that I have read and agree to the above terms:

No
Yes

BNEVO