**PROTOCOL**

**Experimental / Clinical Research**

1- The researcher declares, undertakes and agrees to comply the rules of Başkent University Research Center and the Principles of Başkent University Experimental / Clinical Research in the research and studies carried out within Başkent University. The researcher declares, undertakes and agrees the application of Başkent University Experimental/Clinical Research Principles and Research Center rules in case of conflicts.

2- The University agrees to provide the convenient environment and facility to researcher for his/her study in accordance with the legal regulations of Başkent University Experimental / Clinical Research Principles and Research Center rules. Furthermore, it declares, undertakes and accepts the application of Experimental/Clinical Research Principles and Research Center rules in legal disputes to arise.

3- Başkent University Experimental / Clinical Research Principles and Research Center Rules are an integral part of this protocol.

4- Ankara Courts and Enforcement Offices are authorized in disputes arising from this protocol.

This protocol was signed between the parties in Ankara on… ../… ./ .. …….

Name and surname of the Project Manager Dean / Manager

**BAŞKENT UNIVERSITY PRINCIPLES OF CLINICAL RESEARCH**

For clinical research to be conducted at Başkent University, certain regulations have been stipulated by Başkent University Medical and Health Sciences Research Board. These regulations are outlined below and each researcher must follow carefully and carefully. Medical research on people using drugs is subject to the provisions of the relevant regulation.

**Definitions**

**Subject:** Volunteers, patients, people who are likely to become ill with an intervention for experimental purposes.

**Clinical investigator:** specialist physicians who conduct or actively participate in Clinical Research, who have direct authority to intervene with the patient.

**University:**Başkent University

**Rectorate:**Başkent University Rectorate

**Research Board:**Başkent University Medical and Health Sciences Research Board.

**Article 1.** Experimental or clinical researches to be carried out at Başkent University may be conduct with the approval of the Research Board. For this, researchers should apply to the Medical and Health Sciences Research Board with a detailed project proposal. This project proposal should include:

a) The subject and purpose of the research,

b) The duration of the research, estimated attendance time of the patients or volunteers,

c) A summary of the procedures to be followed (including the use of a placebo) and the specific definition of any proposed experimental (ex. nonstandard) procedure,

d) The definition of the risks and disturbances (including those predicted in the protocol) that the research may cause to the subject,

e) To identify the possible benefits that the research may provide to the patient, person or others,

f) The description of the risks and benefits of alternative treatment methods that may be advantageous for the patient.

**Article 2.** In human researches;

a) It must be for a therapeutic purpose.

b) If the application is hazardous despite the fact that it has been tried sufficiently, there will be a situation where there is no other opportunity to save the patients in performing such experiments.

c) The experiment should be planned according to the generally accepted rules of the medical profession and the current state of the medical science, and should not be contrary to the custom, and consent should be obtained from the experimenter.

d) Experimental studies should be carried out on human beings in cases where human health cannot be protected by the present data, and even in this case where experimental studies do not foresee severe results.

e) Placebo therapy should not be used for experimental purposes in patients who are required to be treated with drugs.

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Chapter II, Articles 9 and 10 of the “regulation on Drug Research " published by the Ministry of Health in the official gazette No. 21480 dated 29 January 1993

**Article 3.** Getting approval of those to be included in the research.

a) The researcher must obtain the written consent of the patients or persons to be included in the research.

b) For children, in such a case, the written approval of the mother and father or, if any, of the Guardian and legal institutions should be obtained.

c) For individuals who are mentally unstable or whose approval cannot be obtained for any reason at the time, the written approval of their parents or guardians or, if any, their legal institutions must be obtained.

d) In these approvals, the whole scope and possible risks and outcomes of the experimental and research for the purpose of treatment should be included, and in the approval it should be clearly stated that the application was carried out in the experiment together with the purpose of treatment.

**Article 4.** The researcher should ensure that records (identifying to the relevant departments, if there are legal grounds) that identify the patient or person who will participate in the research are protected.

**Article 5.** The researcher should immediately cease the research at any stage when necessary.

**Article 6.** The patient or person (or the pregnancy, embryo or fetus at that time or in the future) should be informed of the risks of a special treatment, the severity and extent of which cannot be predicted.

**Article 7.** Any change that made before or during the project should be reported to the Research Board and/or the relevant persons (the administration and the patient himself or his / her parents).

**Article 8.** Before starting the research, each patient or volunteer should be informed in detail about the research.

**Article 9.** The patient or volunteer should be given full information on their medical condition, alternative treatments and details of the protocol.

**Article 10.** No clinical research can be conducted for the production or development of all kinds of weapons, ammunition, and cigarettes.

**Article 11.** When working with carcinogenic, toxic or infectious material, collaborators should be informed in advance of possible risks and precautions, and no attitudes or behaviors that pose a risk to co-workers or others should be taken.

**Article 12.** The researcher should take appropriate precautions against possible risks for himself, volunteers, and colleagues during research.

**Article 13.** All legal and financial responsibilities of the research belong to the persons, institutions and organizations that carry out and support the research.

**Article 14.** In studies not supported by Başkent University, any material expenses to be used will be covered by the researcher.

**Article 15.** Unauthorized information and /or documents should not be provided to third parties in all works supported by Başkent University in any way or performed in units of the University.

In relation to the inventions and innovations to be revealed in this type of work;

a) Any right of publication and notification requires the written permission of the rectorate.

b) Patent rights belong to the University.

c) In cases where a patent is required to be obtained in relation to the inventions and innovations that arise as a result of the studies, the participants are given a share by taking their contributions into account. The way and rates of the share are determined by the rectorate.

d) The above rules also apply to researchers who are disconnected from the University.