

Ethics Committee Directive on Non-Interventional Studies

TC BEZMIALEM VAKIF UNIVERSITY

INITIATIVE INVESTIGATIONS ETHICAL INSURANCE

GUIDANCE ON THE WORKING PROCEDURES

Goal

Article 1- (1) The purpose of this Directive is; BEZMIALEM All non-drug observational studies, methodological studies, survey studies, retrospective archive scans such as file and image records, biochemistry such as blood urine, tissue, radiological images, microbiology, pathology, and radiology collection materials or routine examination, examination cell or tissue culture studies with investigations to be made with materials obtained during the analysis and treatment procedures; gene therapy to be performed with genetic material that is outside of clinical research and that is intended to identify

researches in the field of all health sciences and other research areas related to the field of health, diet studies with food additives, researches on body physiology such as exercise, studies done based on anthropometric measurements and studies on the evaluation of life habits, all researches to be done without human intervention to examine in line with ethical principles and rules, to express opinions, to observe,

initiative, which is established to terminate, to make decisions, to create new principles and rules when necessary

Determine the establishment and working principles of the Non-Research Ethics Committee.

Scope

Article 2- (1) This Directive shall be applied to investigations in the scope of article 1 to be carried out at BEZMIALEM Vakif University, in accordance with the legislation on the protection of the rights of patients and voluntary individuals, the rules to be followed and basic principles, the examination of ethical cross- methods and principles related to decision making and monitoring, principles of establishment and working of the Ethics Committee, related institutional and individual responsibilities and responsibilities.

Substrates

Article 3- (1) This Directive shall be amended by the Regulation on Patient Rights published in the Official Gazette dated August 01, 1998 and numbered 23420, Regulation on Clinical Investigations published in the Official Gazette dated 13 April 2013 and numbered 28617 of the Ministry of Health and Official Gazette dated February 15, 2014 and numbered 28914 The Regulation on the Working Procedures and Principles of the Ethical Committees of Animal

Experiments prepared by the Ministry of Environment and Fobase published in Gaziantep was prepared on the basis of.

Definitions:

Article 4- (1) In this Directive;

a) Ministry: T.C. The Ministry of Health,

b) Chairman: BEZMIALEM Vakif University, Chairman of the Ethics Committee of Non-Interventional Studies,

c) Ethics Committee: BEZMIALEM Vakif University Non-Interventional Research Ethics Committee,

d) Non-invasive research: Work is the research described in article 1 of this directive.

Formation of Ethics Committee:

Article 5- (1) The Ethics Committee consists of at least nine members proposed by the University Senate and appointed by the Rector. The members of the Ethics Committee have been in office for four years and the termination member can be reassigned.

A member who does not attend three consecutive meetings without permission in a calendar year shall be dismissed and replaced by the new member in the same manner.

(2) Members elect one from among themselves. The President appoints one of the members as rapporteur. In the absence of the President, the most senior lecturer is the President.

Meeting Procedure and Decision of the Ethics Committee

Article 6- (1) Upon the invitation of the Chairman, the Ethics Committee shall convene at least once a month with the participation of at least two thirds of the total number of members and the decisions shall be taken by the majority of the total number of members attending.

BEZMIALEM Vakif University Guideline on Working Principles of Non-Interventional Research Ethics Committee

Working Principles of the Ethics Evaluation Board

Article 7- (1) The research proposal coming to the Ethics Committee shall be evaluated at the first meeting. The Ethics Committee,

may invite the researchers or experts concerned with the research proposal that they are examining if they see it, by inviting them to their meetings. If necessary, the research proposals may be sent to relevant experts in advance to evaluate them scientifically.

(2) Ethics committee; it ethically examines and decides the applications. The work to be done is started after the approval of the ethics committee. While discussing the research proposal of members of the Ethics Committee, the related board member can not participate in the discussions and vote.

(3) The research proposal, whose correction or deficiency should be completed, is corrected by the researchers and given to the Ethics Committee in duplicate and reevaluated at the first meeting made by the Ethics Committee.

(4) When the Ethics Committee decides, it considers all relevant legal regulations, professional codes of ethics, national and international declarations and notices and ethical values and principles.

Monitoring of Research

Article 8- (1) The development report may be requested when it is deemed necessary for the researches approved by the Ethics Committee. The responsible investigator is responsible for the preparation of these reports.

(2) The Ethics Committee reviews these reports and examines whether the research is conducted in accordance with the rules.

(3) As a result of the examinations of the Ethics Committee, it is possible to stop the researches which are understood as not conforming to the ethical rules and to inform the related departments

Non-institutional Applications

Article 9- (1) When an application is filed outside the institution, a fee shall be paid for the evaluation expenses. The amount of the fee is determined each year by the Senate of the BEZMIALEM VAKIF University.

Enforcement

Article 10- (1) This Directive shall enter into Enforcement on the date of acceptance by the University Senate.

Executive

Article 11- (1) The provisions of this Directive shall be executed by the Rector.