Directives for Clinical Research and Scientific Advisory Services Supported by BEZMIALEM Vakıf University

BEZMIALEM VAKIF UNIVERSITY

CLINICAL RESEARCH AND SCIENTIFIC CONSULTANCY SERVICES TO BE SUPPORTED BY THE SUPPORTER

DIRECTIVE

Purpose and Scope

Article 1- The aim of this regulation is to determine the procedures and principles of clinical researches, observational studies and scientific consultancy services carried out by supporting faculty members and researchers at BEZMIALEM Vakıf University, and includes the works to be done for this purpose.

Base

Article 2- This directive has been prepared on the basis of Article 37 of Higher Education Law No. 2547.

Definitions

Article 3 - In this regulation,

a) Scientific study: Scientific opinion, clinical research, observational research, project and similar services,

b) Promoter: Real and legal persons who are responsible for financing the initiation and execution of a work or requesting a scientific consultancy work,

c) Dean: The faculty dean of scientific studies,

d) Evaluation Committee: The "Evaluation Committee for Clinical Investigations and Scientific Advisory Services to be Performed with the Supporting Institution", which will be formed by the university rector to evaluate the scientific studies to be carried out within the scope of this directive within the university,

e) Scientific field: The faculties, colleges, institutes, hospitals and similar places belonging to the universities,

f) Responsible Investigator: Persons who are responsible for the conduct of the research in scientific studies and who have received field specialization or doctoral studies in relation to the research to be carried out,

g) Auxiliary researcher: At least undergraduate students who are included in the study team determined by the responsible researcher for the conduct of scientific studies

h) Regulation: The Ministry of Health Turkey Pharmaceuticals and Medical Devices Agency, which was published by the Clinical Trials Directive refers.

General Principles and Types of Work

Article 4- (1) As clinical research and scientific advisory services to be carried out with supportive requests,

a) Clinical trials planned in line with the clinical trial guidelines,

b) Observational studies,

c) Survey and registration studies,

d) Scientific consulting services,

e) Scientific presentations and opinions to be held at conferences and meetings,

f) Scientific courses and seminars,

g) Services to be provided in visual and written media and similar activities are defined as income generating activities.

(2) The activities supported by ministries and public institutions such as TUBITAK are outside the scope of this directive.

(3) All work and services to be performed should be planned in accordance with the Clinical Research Regulations and Ethical Rules.

Clinical Research and Scientific Advisory Services Evaluation Board

Article 5- (1) The university is composed of at least 3 faculty members, faculty, institute and Health, Application and Research Center affiliated to the university determined by the Rector. One of the members of the Board is elected president.

(2) The Board shall be convened at adequate intervals in accordance with the number of applications and shall conclude the applications within 15 days.

(3) Appropriate opinions of the board related to the subjects not mentioned in this regulation shall be taken.

Application

Article 6- (1) Regarding the scientific studies included in the paragraphs 4, a, b and c of the Directive, the Evaluation Board shall be applied by the supporting or responsible investigator.

(2) In the application file, there should be a research protocol, a working budget form, a contract example and an ethics committee decision.

(3) The Ministry of Health in accordance with the Clinical Research Regulations may initiate work requiring permission, after this authorization.

(4) For the activities covered by Article 4, d, e, f and g of the Directive, the sponsor or the relevant faculty member shall apply to the Evaluation Board. An example of the contract to be prepared in this regard should be presented in the application.

Financial provisions

Article 7- (1) In connection with the research, the fee for the research product and, if any, the comparison product and any fees related to the test, laboratory and similar services to be made thereon shall not be billed for SGK and similar public funds and budget or private insurance. Research fees are paid by the sponsor to the institution's account for the period specified in the contract after each service and product is applied or used. Service fees are determined by the "Evaluation Board".

(2) The payment schedule for the research fee related to scientific studies is determined by contract. Taxes and other incomes to be incurred within the scope of payments shall be deducted from the payment to be made. After deducting VAT from the contract price, 70% of the remaining amount is grossly paid to the researcher.

(3) 30% of the income generated by services performed in the fields of radiology, nuclear medicine, pathology and other clinical fields (cardiology, eye diseases, skin diseases, etc.) which are related to scientific studies and which require additional reporting is paid grossly.

(4) Payments to be made to the researcher who conducts the work shall be paid within 3 months following the date of collection of the work.

(5) Payments to be made within the scope of research and consultancy services shall be made without being associated with other income of the researcher (salary, performance payment, progress bill etc.).

Liabilities

Article 8- (1) The sponsor and the responsible investigator shall take necessary measures to ensure that the fee for the research product and the fee for the comparison product, the test, the laboratory and similar services to be related to it, are not invoiced to SSI and similar public funds and budget or private insurance. The sponsor and the investigator will be responsible for any liability that may arise in the future.

(2) The financial provisions and obligations contained in this directive shall also be found in the Convention.

Mechanism

Article 9- The execution of the clinical research and consultancy service shall be carried out as follows:

1-Clinical research or counseling service is submitted to the "Clinical Research and Counseling Services Evaluation Committee" after the request, researcher or consultant approval.

2-The board receives the request with the supplementary request of the secretariat, registers it with the registration number and sends it to the chairman of the "Evaluation Board".

3-The Evaluation Board examines all aspects of the study and the request, reports the opinion and submits it to the faculty dean of the worker to be approved.

4- In case the instructor who is assigned to the Evaluation Board is a researcher, the relevant researcher can not participate in the committee.

5 - BEZMIALEM The Center for Health, Application and Research of the VAKIF University, BEZMIALEM VAKIF University Dental Practice and Research Center is responsible for allocating appropriate areas for clinical study, defining the work to HBYS, making the work appropriate for the rules, invoicing the services given to patients, public or private insurances shall not be invoiced.

Enforcement

Article 10 - This directive shall enter into Enforcement on the date of acceptance by the University Senate.

Executive

Article 11- This directive is administered by the Rector of the BEZMIALEM VAKIF University.