

**İSTİNYE UNIVERSITY  
CLINICAL RESEARCH CENTER DIRECTIVE**

**CHAPTER 1  
General Provisions**

**Purpose**

**ARTICLE 1 – (1)** This Directive regulates the purpose, establishment and operating principles of Istinye University Clinical Research Center.

**Scope**

**ARTICLE 2 – (1)** This Directive covers the provisions regarding the purpose, establishment, operating principles, areas of activity, organs and duties of the Istinye University Clinical Research Center.

**Basis**

**ARTICLE 3 – (1)** This Directive has been prepared based on Article 14 of the Higher Education Law No. 2547 dated 04 November 1981.

**Definitions**

**ARTICLE 4 – (1)** In this Directive,

- a) "Advisory Board" refers to the Central Advisory Board,
- b) "Center" refers to the Istinye University Clinical Research Center,
- c) "Director" refers to the Center Director,
- d) "Rector" refers to the Rector,
- e) "University" refers to Istinye University,
- f) "Board of Directors" refers to the Central Board of Directors.

**CHAPTER 2**

**Purpose and Fields of Activity of the Center**

**Purpose of the Center**

**ARTICLE 5 – (1)** The unit's purpose is to conduct research and development activities in the field of basic and applied sciences related to drugs and other treatment methods and to coordinate the activities and provide training and expertise in these areas.

**Fields of Activity**

**ARTICLE 6 – (1)** The center carries out the following activities:

- a) In our country and at Istinye University, problems arise in operating and managing research on drugs and other treatment methods and translating the results into practice. Istinye University Clinical Research Center will actively contribute to solving problems regarding research organization, coordination and application.
- b) There is a significant gap in our country in terms of conducting pre-clinical studies with new products and methods, as well as phase I studies of products and methods with demonstrated pre-clinical effectiveness. Istinye University Clinical Research Center will align and coordinate these studies to eliminate this gap.
- c) Istinye University Clinical Research Center will act as a facilitating organization and corporate entity that effectively manages phase II, phase III and phase IV trials.

- d) Istinye University Clinical Research Center will coordinate research and its multidisciplinary application by bringing together university faculty members, researchers, assistant researchers, and administrative and technical personnel.
- e) Istinye University Clinical Research Center will conduct research required by the pharmaceutical industry and healthcare sector and will provide services required by national legislation.
- f) Istinye University Clinical Research Center will provide postgraduate education and training for different stakeholders in its field.

### **CHAPTER 3**

#### **Management Bodies, Duties and Personnel Needs of the Center**

**ARTICLE 7** – The Center is governed by the University

- 1) Director
- 2) Board of Directors
- 3) Advisory Board (formed with the approval of the Rectorate upon the Board of Directors' recommendation)

**ARTICLE 8** – Center Director and Deputy Director

- (1) The Rector appoints the Director from University personnel who have knowledge and experience of the activities carried out at the Center. The term of office of the Director is three years.
- (2) The Director nominates a member of the Board of Directors to become the Deputy Director by the Rector's appointment. If the Director leaves his position temporarily, the Deputy Director acts in his stead as Deputy. If Director leaves his position for more than six months, a new Director is appointed.

**ARTICLE 9** - Duties of the Director

- (1) The Director is primarily responsible to the Rector for overseeing and executing activities that advance the mission and objectives of the center. The Director supervises and controls all activities of the Center.
- (2) The duties of the Director are:
  - a) To carry out all the activities of the Center within the mission and vision of the University and the Center; and to represent the Center; and to chair the Board of Directors.
  - b) To determine the Center's work program, short, medium and long-term goals and to submit these to the Rector for approval after receiving the approval of the Board of Directors.
  - c) To prepare the year-end activity report and the work program for the upcoming year for submission to the Rector for approval after receiving the approval of the Board of Directors.
  - d) To manage the units and personnel in its purview according to the objectives of the Center.
  - e) To develop education and interdisciplinary research activities through cooperation with University academic units and public and private institutions.
  - f) To define the budget and personnel needs of the center and submit these to the Board of Directors for approval.
  - g) To fulfill the duties assigned by the Rector according to the relevant legislation.

**ARTICLE 10 - Board of Directors**

(1) The Board of Directors consists of five members. It includes the Director and academicians and other experts operating in the field of study of the Center. Members of the Board of Directors are nominated by the Director and appointed by the Rector.

(2) The term of office of the members of the Board of Directors is three years. Members whose term has expired may be reappointed. When a member departs before his term ends, a new member is appointed to complete the vacated term.

(3) The Board of Directors meets at least twice a year; the Director may convene the Board whenever necessary. The Board of Directors meets with absolute majority and decisions are taken by majority vote. In case of equal votes, the Director's vote carries the decision.

**ARTICLE 11 - The duties of the Board of Directors are:**

- a) To evaluate and make suggestions about the activities proposed to be carried out within the Center and to contribute to the planning and execution of planned academic activities.
- b) To prepare information programs and training in the field of clinical research and to develop facilitating implementation programs for the cooperation of relevant units.
- c) To evaluate the year-end activity report prepared by the Director.
- d) To evaluate and adjudicate the issues proposed by the Director regarding the Center.
- e) To coordinate, evaluate, make suggestions and define the annual plan and the programming, operation, personnel, and budget of the center.

**CHAPTER 4**

**Miscellaneous and Final Provisions**

**ARTICLE 12 - Force**

This Directive is effective upon approval by the Istinye University Senate.

**ARTICLE 13 - Executive**

The Rector of Istinye University executes the provisions of this Directive.