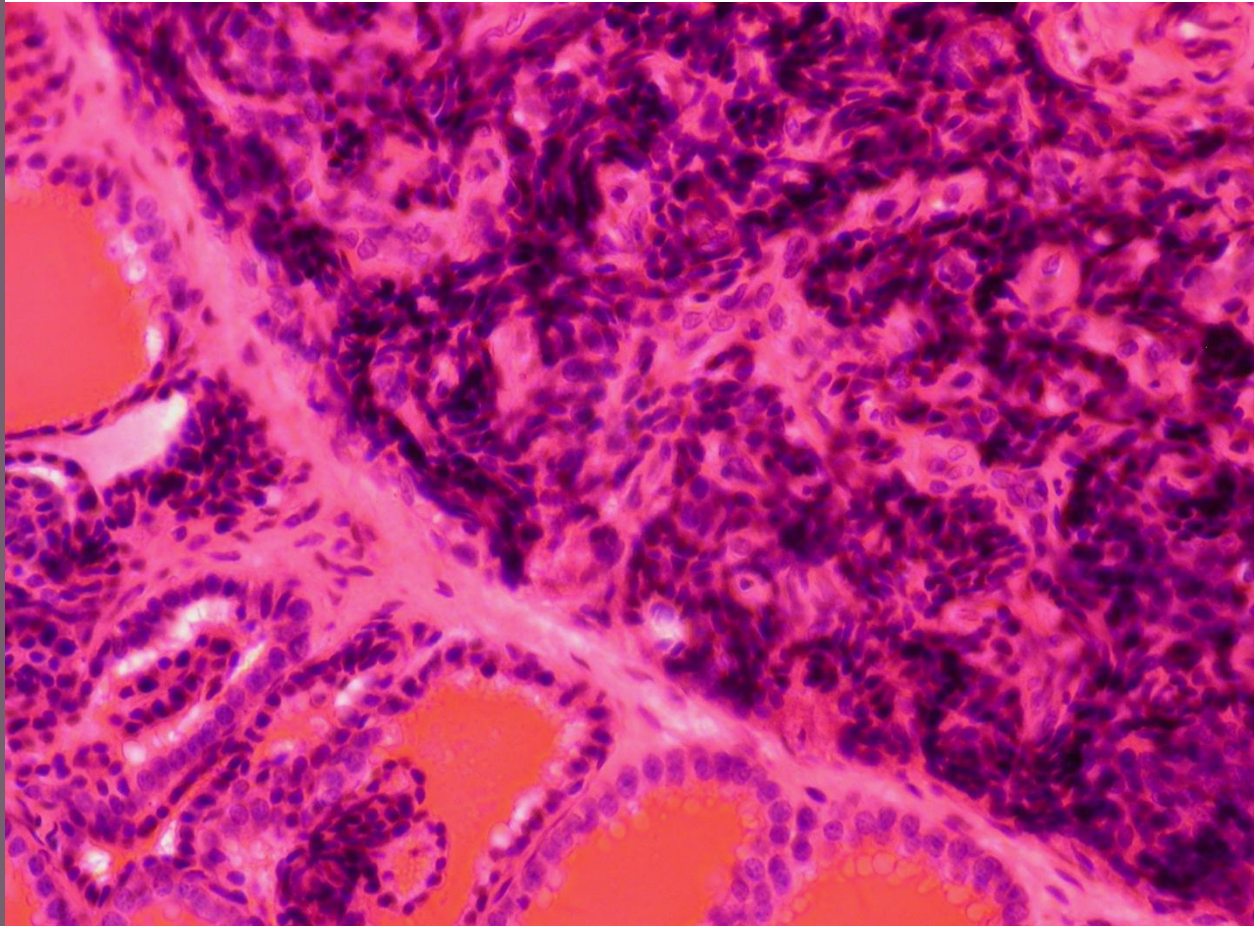


# THE MONITORING OFFICE FOR RESEARCH AND RESEARCH ETHICS AT UNIVERSITY OF DAMMAM

The Implementing Regulations for the Monitoring  
Office for Research and Research Ethics

G 2014 - H 1435



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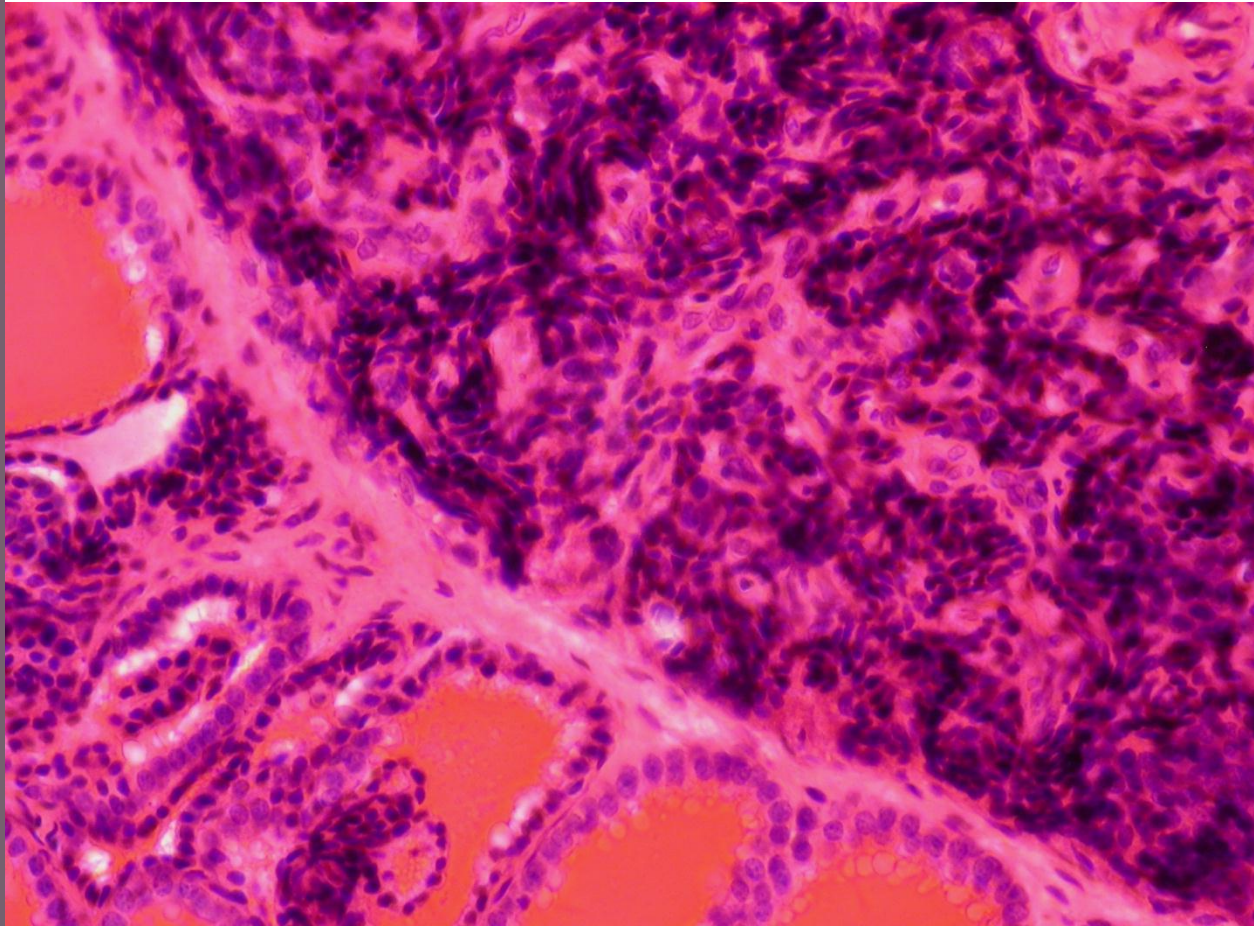
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## Introduction

**The University of Dammam (UOD) as a research institution under the guidance of Prophet Muhammad (May Allah's prayers and peace be upon him) who said “Allah loves that if one does a job he perfects it” seeks to excel in research to have results that are based on scientifically sound research methods. To achieve this objective UOD has focused not only on outlining the policy of scientific research, but also to attain a vigorous pace for the development and application of measures to ensure the mastering of research through implementation. In addition to the importance of establishing the necessary safe research environment, UOD has adopted both relevant local regulations and international standards to have a suitable working environment and ensure the safety of human and living creatures involved in research. University of Dammam has formed a Standing Committee for Research Ethics on Living Creatures to abide by the Kingdom’s law of Research Ethics on Living Creatures. The National Committee of Bioethics has also established a Monitoring Office for Research and Research Ethics as a guide for the researchers to work according to the rules, regulations and ethics that are required to ensure the quality of scientific research intended to be conducted at their research institutions. UOD is working to achieve the set objectives of its strategic plan to be not only a first class educational and a research institution, but also to significantly contribute to scientific knowledge in order to achieve the goals of social development through adopting quality research, to have scientifically sound publishable results. The University aims to be seen as a home of great minds and a global research beacon with the grace of almighty Allah.**

## Definitions

**The following terms and phrases , wherever used in this document, shall have the meanings assigned to them, unless otherwise required by context.**

**Law:** Law of Ethics of Research on Living Creatures.

**Regulations:** Implementing Regulations of the Law of Ethics of Research on Living Creatures.

**President:** President of the University of Dammam

**Implementing Regulations:** Implementing Regulations of Biomedical Ethics.

**Monitoring Office:** Research Ethics Monitoring Office.

**Standing Committee:** Committee for licensing the research formed at the University of Dammam in accordance with the provisions of this Law.

**Establishment:** A public or private corporate entity engaged in research activities on Living Creatures.

**Researcher:** A person academically qualified in a subject related to research and has completed a course on research ethics.

**Research:** A systematic experimental investigation aiming at the improvement of biosciences, and enrichment or development of general knowledge by using a living creature or parts thereof.

**Living Creatures:** Human beings, animals and plants.

**University:** The University of Dammam



## **Administrative Decisions**

**“The Monitoring Office for Research and Research Ethics” has been established as per the President’s administrative decision No.57750 dated: 1/11/1435H.**

## **The Goals of Monitoring office for Research and Research Ethics**

**Ensuring the conduction of research according to the implementing regulation for research on living creatures at the University.**

**Coordinating between the Standing Committee for Research Ethics on Living Creatures and researchers**

**Representing the Standing Committee in the colleges and institutions of the University in which the vital research will be conducted by the executive committees.**

## **The Monitoring office for Research and Research Ethics: tasks at the University of Dammam**

### **The Monitoring Office shall:**

- 1- Monitor the implementation of research ethics at the University's facilities and/or supervised by the University.
- 2- Conduct periodic ethical evaluation and monitoring of laboratories at different colleges and institutions of the University.
- 3- Register and oversee local committees in accordance with the implementing regulation for the ethics system on living creatures at the University.
- 4- Conduct periodic ethical evaluation and monitoring of medical and pharmaceutical laboratories on Living Creatures to ensure legitimacy thereof.
- 5- Coordinate with research concerned authority to ensure compliance with the biomedical ethics on research.
- 6- Prepare periodic educational programs and consolidate awareness among researchers in matters pertinent to the regulations and operational procedures for research ethics system.
- 7- Prepare executive plans to ensure compliance of the research teams with the Law and Regulations of Ethics
- 8- Ensure the implementation of protection and safety regulations for humans and living creatures which are under consideration.

- 9- Coordinate between the research committees and researchers and between the Standing Committee of Research Ethics on Living Creatures at the University.
- 10- Record any damage or violation committed by the research committees, and reports this to the Standing Committee to take the necessary action.
- 11- Prepare periodic reports about office work and submit this to the Standing Committee of Research Ethics on Living Creatures.
- 12- Perform any other tasks assigned thereto by the Standing Committee of Research Ethics on Living Creatures.

## **Implementing Regulations of the Monitoring Office for Research and Research Ethics at the University of Dammam**

### **Article 1 \*:**

**Based on Article 8 of the Law of Ethics of Research on Living Creatures a Monitoring Office for Research Ethics and its committees shall be established, under the Standing Committee of the University of Dammam, by a decision from the Vice President for Higher Studies and Scientific Research and Chairman of the Standing Committee of Research Ethics on Living Creatures of the University. Based on the recommendation of the Standing Committee, the Monitoring Office for Research and Research Ethics of the University shall be chaired by a specialist with experience in medical and scientific research and research ethics.**

### **Article (1.1)**

The Monitoring Office shall report to the Chairman of the Standing Committee of Research Ethics on Living Creatures of the University.

\* Corresponds to Article 8 of the Law of Ethics of Research on Living Creatures.

### **Article (1.2)**

The President shall appoint, upon a recommendation by the Chairman of the Standing Committee, a full-time director for the Monitoring Office with experience in medical and scientific research and research ethics.

### **Article (1.3)**

The Monitoring Office may establish executive committees in different colleges and institutions of the University, subject to satisfying of the following conditions:

- 1- The need for establishing an executive committee in the relevant college.
- 2- Financial allocations required for establishing and operating the executive committee.
- 3- Submission of a recommendation by the Standing Committee to the President of the University stating the need for establishing such a committee.

The executive committees may be established at colleges other than at the main campus of the University to conduct research but to be supervised by the University.

### **Article (1.4)**

The Monitoring Office shall have an adequate share of the financial allocations set for the Standing Committee to pay for its activities.



## **Article 2 \*:**

**The Monitoring Office shall be in charge of the following:**

- 1- Register and oversee the executive committees in the colleges and institutions in accordance with the Implementing Regulations of the Law of Ethics for Research on Living Creatures of the University.**
- 2- Monitor the implementation of research ethics subject to this Law.**
- 3- Any other tasks assigned thereto by the Standing Committee.**

**The Regulations shall specify the Office rules and procedures.**

### **Article (2.1)**

The Monitoring Office shall register and oversee executive committees and monitor their compliance with the provisions of the Law and its Regulations as well as the controls and procedures set by the Standing Committee

### **Article (2.2)**

Registration of the executive committees (colleges, institutions, hospitals, and centers) shall be in accordance with the following procedures:

- 1- The Monitoring Office shall prepare a form containing the Committee's information to be published on the Standing Committee's website. The information shall include the following:

\* Corresponds to Article 9 of the Law of Ethics of Research on Living Creatures.

- a) Name and address of the formed committee..
  - b) Date of formation.
  - c) Nature of researches conducted at the college or institution.
  - d) Names and CVs of the committee chairman/ chairperson and members.
- 2- The college applying for forming an executive committee shall complete the form referred to in Paragraph (1) above, provide the necessary data, and submit the form along with any necessary documents, including the decision of forming the committee, to the Monitoring Office of Research.
  - 3- The Monitoring Office shall review each registration application submitted thereto by the committee. If the application data are incomplete, the committee shall be notified.
  - 4- The Monitoring Office shall review the executive committee's registration application within 15 working days from the date of receipt of the completed application, take a decision to this effect, and promptly notify the concerned committee of the said decision. The provided notification should include the registration number and date.
  - 5- The Monitoring Office may not reject any application for registration except on legal grounds. If the application is rejected, the Monitoring Office shall notify the authority with the reasons for rejection.

- 6- The Monitoring Office shall provide all registered committees with the following:
  - a) The Implementing Regulations of the Law of Ethics for Research on Living Creatures of the University.
  - b) Lists of research projects that have been approved by the Standing Committee.

### **Article (2.3)**

In its supervision of registered executive committees, the Monitoring Office may undertake the following:

- 1- Assign any person it deems fit to conduct field visits to the registered committee, college, and/or institution at least once every 6 months for examining committee's documents and papers.
- 2- Assign any person it deems fit to attend committee meetings, if need be.
- 3- Ensure committee compliance with relevant laws, regulations, rules and directives and coordinate therewith for this purpose.
- 4- Review complaints or grievances submitted by the principal investigator or by any member of the research team against committee decisions.
- 5- Review complaints submitted by the human subject in case he/she claims to have been harmed as a result of the research.

#### **Article (2.4)**

In its monitoring of executive committee's compliance with the provisions of the Law and its Regulations, the Monitoring Office may undertake the following:

- 1- Review all records and documents of research registered with the executive committee.
- 2- Contact the participating human subject, if required.
- 3- Cancel, suspend, terminate or prevent executive committee tasks, if necessary.
- 4- Record any violation committed by the committee and takes the necessary actions in accordance with the Law and Regulations.
- 5- Conduct periodic ethical evaluation and monitoring of laboratories in different colleges, and monitor medical research and experiments conducted on Living Creatures to ensure legitimacy thereof.
- 6- Upon the verification of an occurrence of a violation or a reasonable possibility of a valid claim of harm, the Monitoring Office may refer the matter to the Standing Committee to take the appropriate action.

#### **Article (2.5)**

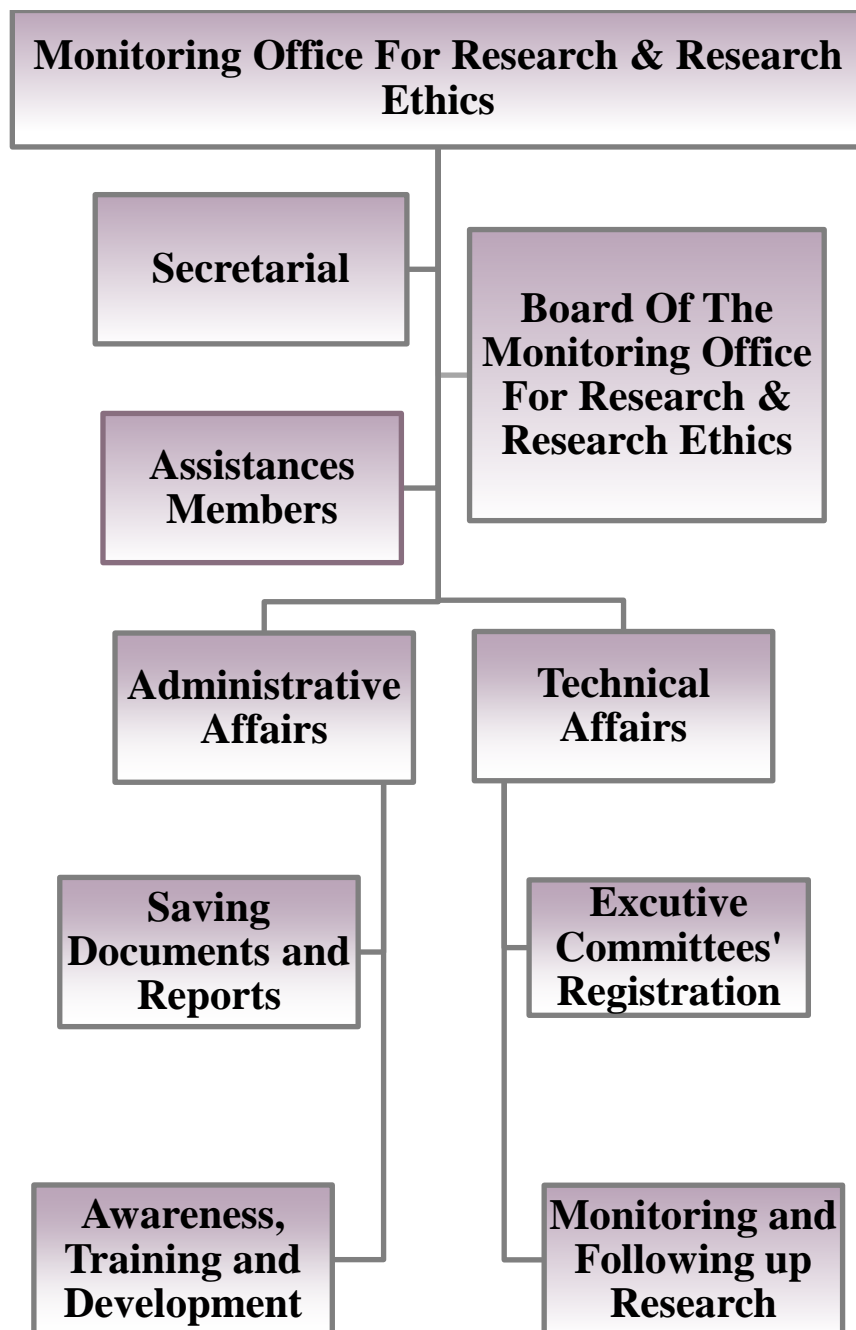
The Standing Committee Chairman shall appoint office staff upon recommendation of the director of the Monitoring Office in accordance with applicable

procedures including office secretariat to help carry out administrative and technical work.

### **Article (2.6)**

The Monitoring Office may, if necessary, seek the assistance of specialists, experts and/or consultants if deems fit, after the notification of the Standing Committee Chairman, and according to the University's applicable rules.

## Organizational Structure for the Monitoring Office for Research and Research Ethics



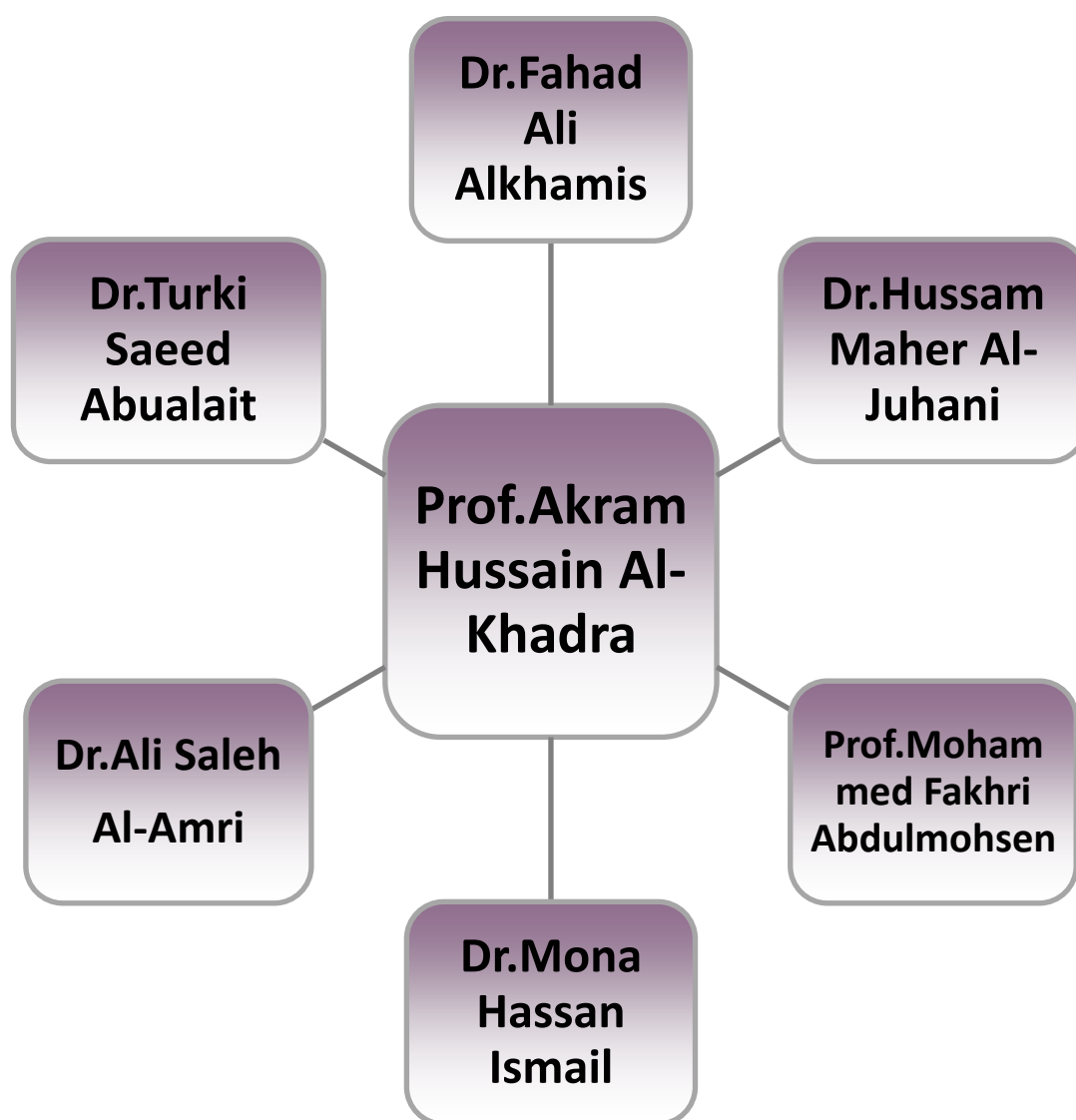


## Administrative Structure

The following figure shows the administrative relationship between The Standing Committee of Research Ethics on Living Creatures, the Monitoring Office, and the Executive Committees:



## Chairman and Members of Monitoring Office For Research & Research Ethics



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