



Policy Inherent in Research Involving Human Participants

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| Reference : | |
| Date of implementation: | |

Table of contents

| | |
|---|----------|
| 1. Introduction | 3 |
| 1.1. Objective(s) | 3 |
| 1.2. Persons and instances concerned Erreur ! Signet non défini. | |
| 1.3. Definitions | 3 |
| 1.4. Legal and statutory context Erreur ! Signet non défini. | |
| 2. Principles | 5 |
| 2.1. Mission and core values of the Antonine University : Erreur ! Signet non défini. | |
| 2.2. Legal compliance Erreur ! Signet non défini. | |
| 2.3. Policy inherent in research involving human participants | 6 |
| 3. Governance..... | 8 |
| 3.1. Responsible Authorities Erreur ! Signet non défini. | |
| 3.2. Verification and Modification History Erreur ! Signet non défini. | |

1. Introduction

In this document, the masculine form refers, as appropriate, to both women and men. The use of the masculine is for the sole purpose of facilitating the reading of the text and has no discriminatory intent.

1.1. Objective(s)

This policy aims to clarify the procedure for processing research projects involving the human person that Antonine University (AU) implements.

1.1. Persons and instances concerned

This policy is applicable to all students, lecturers and researchers and is piloted by the AU Ethics Committee.

1.2. Definitions¹

| Term | Definition |
|-------------------------------------|---|
| Research involving the human person | Any act aimed at the production of knowledge, carried out by experienced researchers or students and involving an intervention on individuals, which may or may not incur risks for them, depending on whether it involves health products, invasive procedures or foodstuffs ("biomedical research"), whether it consists of minimally invasive or clinically observational procedures ("research to evaluate routine care") or whether it is limited to observing or collecting information about individuals ("observational" or "non-interventional" research). |

¹ Reference is made here specifically to the French law no. 2012-300 of 5 March 2012 relating to research involving the human person (known as the Jardé law), as amended by Order no. 2016-800 of 16 of June 2016.

1.1. Legal and statutory context

| Name | Instance and date of promulgation |
|---|--|
| Lebanese Law on Higher Education | Law number 285 promulgated by the Lebanese Parliament, dated April 30, 2014. |
| Charter of Ethical Principles for Scientific Research in Lebanon | Promulgated by the CNRS-L and signed by the universities of Lebanon on 15 July 2016. |
| Organic Statute of Antonine University | Promulgated in 2013 by the Board of Trustees of Antonine University. |
| Status of the Faculty Member at Antonine University | Promulgated in 2015 by the Administrative Council of Antonine University. |
| Rules and Regulations for Scientific Research at the Antonine University, | Promulgated in 2016 by the Administrative Council of Antonine University. |

2. Principles

2.1. Mission and core values of Antonine University (2015):

Antonine University is a Lebanese and Catholic institution, dedicated to developing the talents of young people in the joy of truth.

It accompanies them in the construction of knowledge, know-how and interpersonal skills enabling them to become qualified women and men in the service of society.

It accomplishes this mission with the highest standards of excellence, ethical rectitude and respect for diversity.

It promotes contextualized scientific research and driven professionalism through innovation.

Institutional values

Truth

Dignity

Diversité

Ethics

Excellence

2.2. Legal compliance

The current policy respects the Lebanese Law number 285 on Higher Education, and the *Charter of Ethical Principles for Scientific Research in Lebanon*, promulgated by the CNRS-L and signed by the Lebanese Universities on 15 of July 2016, and is in conformity with the *Organic Statute* of Antonine University, as well as with the mission and institutional values of the AU, such as respect for diversity, ethics and dignity.

2.3. Policy inherent in Research involving human participants in the AU

2.3.1. Composition of the AU Ethics Committee

Antonine University established an Ethics Committee (EC) in October 2016. The Rector annually appoints five to six members to compose the EC, as representatives of the sectors particularly concerned by ethical issues at the AU. The Vice-Rector for Research is a full member of the EC. This committee meets ordinarily once a month and extraordinarily at the request of the Rector or a third of its members. The Rector chairs the meetings of the EC and appoints from among its members a Guarantor of the EC, whose tasks are to convoke the EC on behalf of the Rector, to draft the minutes of each meeting and to organize the work of this instance, in collaboration with the Vice-Rector for Research on issues related to the ethics of scientific research.

2.3.2. Mission of the AU Ethics Committee

The mission of the EC is:

The Ethics Committee (EC) of Antonine University is a committee that aims to promote the ethical values mentioned in the mission of Antonine University, within the different units, in a contextualized form in relation to the disciplines taught, and to ensure that these values are applied.

Research, in particular, which is a central component of the AU's mission, produces knowledge that is generally useful to society. However, the acquisition of certain knowledge requires the participation of individuals whether for interviews, consultation of personal data, medical examinations, questionnaires or observations in their environment. In return, the AU must respect the dignity of the participants concerned and ensure that their rights are respected.

For this purpose, the AU has developed standards to ensure that participants are treated according to the ethical principles of research, including respect for persons and their privacy, concern for human welfare and dignity, and justice. In addition, the EB ensures that intellectual property is respected at the AU, particularly in the tasks of teaching and knowledge production.

Finally, the EC may be consulted in an advisory capacity on questions of ethics in academic and administrative governance.

2.3.3. Tasks and objectives of the Ethics Committee

The Ethics Committee of Antonine University has the following tasks and objectives:

1. to decide on requests for ethical approval of research projects involving human participants from faculty members and/or students of the AU, through the Deans of Faculties and/or the Directors of Research Units;
2. to determine cases of plagiarism and scientific fraud that may be submitted to it by AU instances;
3. to develop consideration of the ethical aspects arising from the practice of research, having regard to its aims and consequences;
4. to propose ethical principles relating to research, teaching and administrative activities, individual behavior, collective attitudes and the functioning of AU instances;
5. to draft/adopt charters and/or regulations on ethical issues;

6. to establish an inventory of the existing situation by collecting data on the implementation of ethical values in the different units;
7. to ensure the implementation of these values in the AU faculties and research units, in terms of research activities, teaching and any action carried out in these frameworks;
8. to take action to encourage the alignment of practices with the reference texts, bearing in mind that the EC has the power to take action on its own initiative in this respect, in accordance with a procedure of last appeal;
9. to set up ethics awareness sessions for faculty members, students and administrative staff.

2.3.4. Procedure for the evaluation of research projects involving human participants

The AU Ethics Committee (EC) decides on the applications for ethical approval of research projects from AU faculty members and/or students that involve human participants. Thus, all projects that request the assistance of participants must undergo an ethical review prior to the recruitment of participants, regardless of the mode of data collection, analysis, or the more or less invasive nature of the research. These projects are submitted to the EC, by filing with the Vice-Rector for Research, no later than two weeks before one of the meetings of the EC (the annual calendar of meetings is published before the end of September of each year). The EC immediately communicates its decision to the requesting instance through the VRR.

Steps of this procedure :

1. The applicant (faculty member or student) fills out a form identifying the research in its various parameters, in particular those that imply its submission to the EC, and signs a 15-point commitment that guarantees respect for the ethical standards of research, inherent to the involvement of human participants.
2. This form is countersigned by a Guarantor, the dean of the supervising faculty or the director of the supervising research unit.
3. The Guarantor submits this request to the EC, through the Vice-Rector for Research (VRR).
4. The VRR communicates the application to the Rector who delegates the evaluation of the said application to a member of the EC, who then acts as Rapporteur.
5. The Rapporteur shall prepare his report at very short notice and present it to the Rector.
6. At the next meeting of the EC, the Rector shall submit the said request to the EC, together with the report, for decision.
7. The EC takes note of the opinion of the Rapporteur and, in the case of a complex or controversial file, discusses the said application for approval, before giving its final argued verdict.
8. The VRR communicates this verdict to the Applicant and the Guarantor.
9. If approved, the research may be conducted as soon as its participants desire.
10. In case the EC expresses reserves, these must imperatively be taken into consideration by the Applicant, who may submit a new application for research approval that effectively addresses the restrictions expressed and which is subject to the same procedure.

3. Governance

3.1. Responsible Authorities

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| Guarantor of the application and updating of the policy | The Vice-Rector for Research and the Ethics Committee |
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3.1. Verification and Modification History

| Version number | Date of approval | Approved by | Amendment |
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