Université Antonine

Ethics Committee

Pre-Approval Request Form for Research Involving Human Participants

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.

Any proposed research within the AU, involving human participants must receive the prior approval of the AU Ethics Committee (*The Antonine University Ethics Committee: Mission and Tasks*).

1. Identification of the applicant

Name and first name of the applicant:

Status:

□ Faculty member piloting a research project

□ PhD student or student

□ Master Student

Faculty or Research unit:

Phone:

E-mail Address:

For students, UA identification number:

2. Identification of the guarantor

Name and First name of the guarantor:

Status:

□ Dean of the Faculty …

□ Director of the Research Unit …

□ Faculty member supervising a student research

Faculty or Research unit:

Phone:

E-mail Address:

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3. Identification of the planned research

Title of the research:

Disciplinary area of research:

Nature of the research (check the corresponding box/es):

☐ Research project led by a teacher-researcher from the AU.

☐ PhD dissertation / Thesis / end of studies thesis.

☐ Research act proposed by an AU student as part of a learning activity, under the responsibility of a teacher.

☐ Other. Explain:

Form of scientific evaluation of which the project has already been the subject:

Is this a multi-center project (involving the review of the project by more than one ethics committee? ☐Yes ☐No

Start and end (estimated) dates of the search:

Funding Source(s):

Places where the research will be conducted (specify the modalities: AU, participants' home, schools, field survey, others):

Abstract (in a maximum of 500 words) of the research project (objectives of the study, methodology, attach the full text of the project in appendix):

4. Reason for the request (research act involving human participants):

☐ **The projected research is based on gathering information from human participants.**

☐ **The projected research relies on the clinical field.**

☐ **The proposed research includes an experimental component that is biological, physiological or psychological.**

☐ **Other. Explain:**

5. Procedures for recruiting participants

Does the project involve recruiting minors?

☐ Yes ☐No

Does the project involve recruiting adults unable of providing informed legal consent?

☐ Yes ☐No

6. Applicant's commitment

I undersigned _____, acting in my capacity of approval applicant for the research project specified above, certifies that the research conducted as part of the above mentioned project will be conducted in compliance with the deontological codes of my profession and with the full respect of the physical and moral integrity of the participants. I also undertake to request the prior approval of the Ethics Committee before implementing any substantial changes that should be made to this project. In addition, I certify the veracity of the information contained in this application concerning this act and therefore, undertake to respect the following:

1- The projected research respects the dignity and the privacy of human participants, especially, ensuring the strict anonymity and confidentiality related to the information involving the identity of the participants.
2- The projected research respects the professional and scientific deontology of the concerned field.
3- The human participants who might be involved in this research, or their legal representatives (for minors and/or adults lacking legal capacity of giving legal informed consent), will be clearly informed (1) of the details of such research, especially the eventual risks, since their participation is strictly voluntary, and (2) that they have the absolute right of withdrawal at any time or at any stage of the study, and this, prior to its conduct (attach a copy of each information form that will be used).
4- The human participants, who might be involved in this research, will be only if they —or their legal representatives (for minors and/or adults lacking legal capacity of giving legal informed consent)— give their written consent of this involvement (attach a copy of each informed consent form that will be used).
5- If a (audio, photo or video) recording of the participants is considered, it would be the subject of a specific form in the consent form.
6- If compensation is provided for participants, an additional document will specify the form (reimbursement of travel expenses, lump sum).
7- The documents related to this research project, including the letters of consent of the participants, will be saved for 5 years after the end of the research.
8- The risks inherent in this research and incurred by the human participants involved will be minimized drastically.
9- The rules of the AU, the *Charter of ethical principles in scientific research in Lebanon*, the values and the contextual traditions, as well as the recommendations of the Ethics Committee, will be scrupulously respected during the progress of this research.
10- The Ethics Committee will be informed of any source of funding that may concern this research.
11- The Ethics Committee will be informed of any ethical problem and any conflict or unexpected event encountered during the progress of the research.

12- The methods and equipment used for such research shall comply with the security specifications inherent to the disciplinary field, with the Lebanese legislation and with the Antonine University rules.
13- If a publication of the results of this research is foreseen, a text will specify in appendix the modes of transmission of these results, by specifying the way the presentation of the results will preserve the anonymity of participants.
14- If the role or functions of the researchers, their kinship or conjugality, are likely to create a situation of real or apparent conflict of interest, a text will set out in annex the proposed solutions in this respect.
15- The applicant for approval guarantees the ethical integrity of the stakeholders and all the personnel involved in such research.

Date _____

Signature of Applicant_____ Signature of the Guarantor _____

7. Annexed Documents

□ Detailed formulation of the research project.

□ Briefing notes of the participants involved and their legal representatives.

□ Consent forms of the participants involved or their legal representatives

□ Posters, announcements, brochures, if applicable to the project.

8. Decision of the Ethics Committee

Date _____

Signature of the Reviewer for the evaluation of the application_____

Signature of the President of the Ethics Committee, the Rector of Antonine University

_____

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9. Application Guidelines for Pre-Approval of Research Involving Human Participants

Note: This section must be removed from the authorization request once the previous sections, as well as the appendices, have been completed.

The preparation of any application for prior approval for a research act involving human participants requires consideration of the following:

Research Subject

Provide details regarding the issue, purpose, hypothesis, type of participants, activities and duration.

Design and methods

- Place.
- Qualification of researchers. Consent of the natural and / or legal persons solicited to participate in the research (documents attached to this form). Number of participants and justification Age of participants - for minors: parental consent form and oral consent (4 to 7 years) or written form of the minor (8-17 years old). The project will lead to results that will improve or better understand the status of the minor participant. The search will lead to generalizable results.
- Prisoners :
    - Research will not put participant at risk.
    - The selection of prisoners is objective and does not expose them to remuneration.
    - No benefits offered to participants who will be able to affect the answers or results.
- Pregnant women.
- Victims of crime.
- People with illness (physically or mentally).
- Exclusion/Inclusion criteria:
- Procedures and measures that will be adopted to ensure the protection of vulnerable participants.

Collection of Data

Survey / Questionnaire

☐Personally ☐Online ☐Email ☐Post ☐Phone
☐Other ways:

Interview

☐Face to face ☐Focus group ☐Oral history ☐Other:

Observation

☐Classroom ☐Workplace ☐Other:

Archived Data:

Tasting:

☐Alcoholic drink ☐Genetically modified product ☐Chemically altered foods

Examination specimen of human tissue

Procedure not yet sure or official

☐Biomedical ☐Psychological ☐Other:

Description:

1- Recordings

☐Audio ☐Video ☐Photo

Purpose of recording:

2- ☐Internet
3- ☐Social media
4- ☐Other:

Recruitment

Need to recruit participants? ☐Yes ☐No

Recruitment methods

☐Personally ☐Media ☐Post ☐Social media
☐Phone ☐Email ☐Other:

Participants approach method:

Criteria for the selection of participants

Authorizations

Consent form (text)

Authorization to access personal files (medical, civil, academic,...) (text)

Procedure

How are you going to proceed? What details remain to be mentioned?

Risks

☐ Interference with privacy
☐ Abuse or breach of confidentiality
☐Physical risk
☐Psychological risk
☐Social risk
☐Economic risk
☐Legal risk
☐Moral risk
☐Financial risk
☐Risk of suspension of medical care
☐Risk of inappropriate action
☐Risk of job loss
☐Other:

☐ Will this project put at risk third parties? Explain

How will you minimize these risks?

☐ Can this project lead to the discovery of a new medical or psychological condition for the participants?

☐ If so how do you plan to deal with this probability?

Resulting benefits of the research

a. To individuals

b. To the society

Data Protection

1- How will you protect the identity of the participants?
2- How will you protect the Data?
3- Where do you plan to save the Data?
4- How long the data will be kept?
5- Who will have access to this data?
6- In case of tissue specimens have been collected, where will these specimens be kept? for how long? Who will have access to these specimens?

Results

1- Publication: Will the results of this research be published? how do you intend to disseminate these results?
2- Financial gains: Will the participants in this project or the researchers reap the financial benefit of this project? Is there a risk of conflict of interest?

Explain