Norms for the submission of projects to the Ethical Committee of FCM-UNL

The Ethical Committee of Faculty of Medical Sciences, New University of Lisbon (CEFCM) presents in this document the procedures required for an adequate submission of research projects. These norms are aimed to facilitate the researchers work, informing them about the aspects that shall, mandatorily, be included in the documents of a Project, and simultaneously, to hogenize and simplify this evaluation. We call your attention to the fact that these norms can be reviewed whenever necessary.

General Information:

- The projects should be send by the Principal Investigator, accompanied by a declaration of the Head of Department / Area of teaching and research or Coordinator of the Master or Doctoral Course where the project will be developed.
- The project will be addressed to the President of the Ethical Committee, Prof. Doutor Diogo Pais, electronically (cefcm@fcm.unl.pt).
- If the project and namely the recruitment of participants take place in other universities and/or health services, permission from those Ethical Committees (if they exist) should be sought, although the CEFCM does not make its decision depend on that of other institutions.
- For any other enquiries you may contact the CEFCM through its email address: cefcm@fcm.unl.pt

Documents to instruct submission:

1. **The Form** sent by the Committee and dully filled (cefcm@fcm.unl.pt).
2. **Brief *Curricula*** of the researchers (mandatory for the principal investigator) documenting the habilitations for the purpose.
3. Declaration of the conditions and **authorization of the places** where the study will take place (when applicable)
4. Financing (finantial agreements)
5. Declaration on politics of results dissemination
6. Timeline of the study
7. **Study Protocol**

Humans

a. Pertinence and question/hypothesis of the study
b. Objectives
c. Assessment benefit/ risk
d. Study design
e. Inclusion of the participants
    i. Inclusion and exclusion criteria
    ii. Recruitment modalities
f. Specifications on data collection
g. Specifications on biological samples collection and their final destination
h. Info text to be provided to volunteers (control and study groups)
i. Text of the informed consent
j. Insurance (when applicable). Include declaration of the insurance entity with reference to the subjects e respective coverage (insurance apolices).
k. Property and protection of the participants data /confidenciality
1. Scientific assessment by external experts (when aplicable).

Animals

a. Justification and question/hypothesis of the study
b. Objectives
c. Methods
    i. Origin and conditions for animals installation
    ii. Number of animals
    iii. Experimental protocol including:
        1. Analgesia/anesthesia
        2. Euthanasia
d. Justification for the nonadequation in the use of alternative methods to animal experimentation
e. Scientific assessment by external experts (when applicable)
f. Opinion of the Animal Facility of the FCM-UNL.