

# Descriptive memory for Research Project, Contract, Thesis, TFM, TFG or other study (delete as required)

Project title
Applicant's name
Name of Supervisor or Tutor (if applicable)
Academic year/
Data submitted to the Ethios Committee of December and Animal
Date submitted to the Ethics Committee of Research and Animal Experimentation (CEI-EA):



# Research Project or Contract, Thesis, TFM, TFG and any other study (delete as required)

Reference (to be filled in by CEI-EA):
Title:
Start date post approval by CEI-EA:
Applicant's name and surnames:
Doctoral programme and research line (doctoral theses only):
Department (as applicable):
Tutor or Director (as applicable). If more than one, give full names:



# 1. INTRODUCTION TO SUBJECT OF RESEARCH PROJECT SPECIFICATION AND GOALS (max. 800 words)

Explain the current state of play of the subject, including:

- Objectives, justification and purpose of the project
- Personnel carrying out the project and their role in the project.
- Whether or not there is any type of insurance for damage
- Whether genetically modified organisms are used, or genetic testing is being carried out
- Whether the research is carried out with stored biological samples (procedure, type and number of samples; whether they pre-date the Biomedical Research Act; whether they come from or will be stored in a biobank).
- Whether oocytes, stem cells, adult or embryonic stem cells including induced stem cells, foetal cells and tissues are used.

## 2. METHODOLOGICAL CONSIDERATIONS

### (Max. 800 words)

Explain the scientific methodology to be used. This should include and take into account:

- Justification of the methodology
- Subjects involved in the project (group or collective to which they belong; how they will be contacted or recruited and how they will be worked with).
- Treatment of the information obtained (traceability of the treatment and method of data dissociation, if applicable).
- For quantitative studies, please indicate the number of subjects to be included, as well as the statistical justification of the sample size.
- The characteristics that these subjects must possess in order to participate (inclusion criteria) and the characteristics that prevent participation in the research (exclusion criteria) if any.
- Schedule (start and planned completion and chronogram).
- The material means and resources to be used (including, for example, questionnaires, participant information sheets, informed consent, negative report of sexual offences in the case of working with minors and all those deemed necessary, and which should be attached as annexes in section 6).

NOTE: In order to carry out the study, when, for example, surveys are included, the software or computer tools provided by the UAH must be used.



Comité de Ética de la Investigación y de Experimentación Animal

**3. ETHICAL CONSIDERATIONS** (Indicate which aspects should be assessed by the CEI-EA. If it has already been assessed by another committee, indicate the institution and the reason for choosing it, and enclose its favourable report.) (Max. 800 words)

#### 4. OTHER CONSIDERATIONS

Any other aspect to be taken into account in the Ethical Committee's assessment process. (Max. 800 words)

5. BIBLIOGRAPHICAL REFERENCES (Max. 10 most relevant)

#### 6. DOCUMENTS TO BE SUBMITTED WITH THIS SPECIFICATION

The applicant must submit the following documents for the CEI-EA's information:

- Application form corresponding to the research to be conducted:
  - Human participants
  - Biobank
- The completed checklist with the list of items that the research protocol or specification must contain, together with the project documentation at the time of applying to the CEI-EA for evaluation. Depending on whether it is a quantitative or qualitative study or both, one or both of the following lists must be completed:
  - Work of quantitative research
  - Work of qualitative research
- The protocols, the information sheet and the informed consent of the participants shall always be drawn up and submitted to the CEI-EA in Spanish, unless the need to use another language is justified, an exception which in each case shall be evaluated and authorised in advance by the CEI-EA.
- If personal data should be treated, the data processing questionnaire must be submitted. It is available at the CEI-EA website and at the Data Protection Unit website.

If the approval of an ethical committee external to the University of Alcalá has been obtained, its favourable report must be submitted.



For more information about "Instructions for assessing ethical aspects of research projects and contracts", consult <a href="Ethical Committee">Ethical Committee</a>: <a href="Forms and templates">Forms and templates</a>.

Applicant(s). Name and electronic signature
Tutor or Director endorsing scientific methodology to be used
Name and digital signature (If more than one full names and signature of each)
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