

Instructions for assessing ethical aspects of research projects and contracts

Overall duty

Any research project, whether self-standing or part of a Doctoral Thesis, TFM, TFG or any other type of study, as well as Art. 83 research contracts, require assessment of their ethical aspects.

The PI must submit an affidavit in which the ethical aspects of the research to be carried out are made clear and request a favourable report from the Comité de Ética de la Investigación y Experimentación Animal (CEI-EA) (Ethics Committee of Research and Animal Experimentation) of the University of Alcalá.

No research project or contract may be processed unless it is accompanied by this affidavit.

Under no circumstances the CEI-EA will issue an assessment report for projects that have already been started or completed if their ethical aspects are affected.

Two examples of a checklist for drafting a protocol for quantitative or qualitative research studies involving human subjects can be found on the CEI-EA website, which can be used as a reference for other applications.

([Click here](#)).

In case of the project be carried out in a UAH teaching hospital, the assessment will be able to be performed by the hospital's Ethics Committee and the UAH CEI-EA will adopt its decision, unless an agreement has been reached for it to be assessed by the UAH CEI-EA. The committee's report together with the application and the project must be submitted to the CEI-EA of the UAH for ratification before starting the project.

If the project is carried out and assessed in a non-UAH hospital, the report must be sent together with the application and the project so that the CEI-EA can decide whether it can be ratified directly.

Application procedure and deadlines

Applications for assessment must be received before the first day of the month in which an ordinary meeting of the CEI-EA is held. These meetings are held in odd-numbered months of the year, starting in January.

A project with formal defects, insufficient information or inadequate scientific methodology will not be evaluated. In this case, it will be returned for correction, the deadline for receipt being the same as indicated in the previous paragraph.

A repetition of formal defects may lead to the application being rejected.

Once the assessment has been carried out, the deadline for receipt of the amendments or clarifications requested is three months. After this period has elapsed, the application will be cancelled and the process will have to start again from the beginning.

Any project whose implementation depends on obtaining funding applied for in a public or private call for proposals will not be evaluated until this funding has been granted. At the time of submitting the application to the CEI-EA, the applicant will receive a receipt so that he/she can complete the procedures of the call.

Documents required

Depending on the type of research to be carried out (human beings, animals, genetically modified organisms or biological agents), the affidavit must be completed on the appropriate standard form available on the CEI-EA website:

- [Project assessment application forms](#)

These forms should be sent to the following e-mail address comite.etica@uah.es, together with a scanned copy of the project specification and all other necessary documentation as specified on each form.

Both the form and the project specification may be submitted in English or Spanish. The English version will be only accepted if it comes from a non-Spanish-speaking person.

The protocols, the information sheet and the informed consent of the participants shall always be written 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 previously assessed and authorised by the CEI-EA.

Protection of personal data

If the Project, Contract, Thesis, TFM or TFG deals with personal data such as names, surnames, images, voice or, especially, data related to health, opinions and beliefs, it will also have to comply with data protection regulations and complete and submit the corresponding questionnaire available on the CEI-EA website and on the website of the Data Protection Unit.

The questionnaire will have to detail in particular; the technical and organisational measures to guarantee the privacy of individuals; the process of anonymisation of the data processed, especially those related to health, biometric data, race, sex, religion or beliefs, and the technical measures adopted to prevent the reversion and identification of participants.

Likewise, it should be borne in mind that it may be necessary to provide the documentation relating to the performance of the so-called Risk Analysis together with the Data Protection Impact Assessment.

Instructions for project tutors and supervisors

When a research project or similar forms part of a Doctoral Thesis, TFM, TFG or any other type of study, the applications for assessment must also be signed by the person who has tutored or supervised it, in order to ensure that the project presents a sound scientific methodology and that it has been properly supervised; otherwise, it will be returned for amendment.

If any of these cases or research contracts involve third parties or entities outside the University, their involvement in the proposal submitted and the relationship or role they will have in the processing of the information obtained must be stated.

If the use of animals is envisaged, at least one person in the group that is to carry out the research must hold a certificate of training in Function D for the design of projects and procedures on animals, issued by the competent authority.

Specific instructions for students

Work final Degree (TFG)

The TFG is one more part of a university education and therefore, in the first instance, it does not require assessment by the CEI-EA, unless the tutor considers it necessary. The reason for this is that it is assumed that the final objective of the study is learning on the part of the students and not the research itself.

If, due to its special characteristics, it is decided to request a report from the CEI-EA for the TFG, the application for assessment must be submitted as for any other research project and the applicant will always be the tutor and not the student.

TFM and Doctoral Theses

To all intents and purposes, these are considered research projects as far as the need to submit to the ethical evaluation of the CEI-EA is concerned.

The applicant will be the student, although in the case of the TFM and for their information, this must be communicated to the Tutor or Master's director.

In the case of both doctoral theses and TFM, the application must also be signed by the Tutor, giving his/her approval of the scientific methodology used.

In the case of doctoral theses, if ethical assessment is required, it must be requested from the CEI-EA once the research plan has been drafted and approved by the supervisor/s of the thesis and prior to its submission for approval by the Doctoral Academic Committee of the corresponding programme.

Once the assessment has been requested from the CEI-EA and regardless of whether it has been carried out or not, the PhD student must present his/her Research Plan to the Academic Committee, attaching proof of said request.

However, even if the Academic Committee approves the Research Plan, the part of the research that requires the approval of the CEI-EA cannot be carried out until the favourable report has been received.

Information and contact

In case of doubt about the need for assessment by the CEI-UAH, please contact the CEI-UAH Technical Office by e-mail (comite.etica@uah.es).