Guide to completing Form 11 · Teaching research

Before you start

The application

The form is no longer completed entirely by hand. Project information is entered in the **Research Ethics Committee application** and some of the fields are filled in automatically from it. This version is transitional until the application comes into operation.

FILLED IN AUTOMATICALLY

- Title of the activity and the declaration “DOES involve teaching research”.
- Details of the person responsible: full name, institute or department, building, telephone, email, and the signature and date field.
- Answer to section 5 on artificial intelligence.
- List in section 6.7: researchers, courses, degree programme and ERT.
- Boxes for the documentation accompanying the application.

YOU WRITE. Sections 1 to 4 and 6.1 to 6.6.

Who submits it. The form is completed and submitted by the person acting as principal investigator of the project.

Personal data. Under the LOPDGDD (Spanish Organic Law 3/2018), personal data are any numerical, alphabetical, graphic, photographic, acoustic or other information that can identify a natural person, on its own or combined with other information. If the project uses data of this kind, section 2 must be completed.

Initial declaration

The first page is generated from the data in the application: title of the activity, declaration that it involves teaching research, and contact details of the person responsible.

WHAT TO DO

- Check that the title matches the project title (for a PIME, the one in the award).
- Check that the contact details are correct.

Section 1 · Information for all projects

1.1 · Scientific justification

Brief justification of the project, including the **starting hypothesis**, the research **objectives** and the relevant **background**. Maximum 3,000 words.

You can start from the project report (for example, the PIME one), but the hypothesis should be stated explicitly in one sentence.

1.2 · Methodology

Describe the methodology of the study, **with particular emphasis on the aspects with the greatest ethical implications**.

WORTH DETAILING

- Which teaching activity is introduced and what is measured before and after.
- Which instruments are used: knowledge tests, surveys, interviews…
- Whether all groups receive the same activity or there is a control group. If there is one, justify it in 1.6.

1.3 · Recruitment

TYPE OF RECRUITMENT

Prospective (before the event of interest, with follow-up, such as a pre-test / post-test), **cross-sectional** (at a single point in time, such as a survey), **retrospective** (using existing data) or a combination.

WHAT TO EXPLAIN

- **Who recruits** and whether they have a relationship with participants (do they teach the course where recruitment takes place?).
- **Inclusion and exclusion criteria**. For example: all students on course X who agree to take part, excluding (or not) exchange students.
- **Process**: when recruitment takes place (during teaching? once grades have been released?), what is explained and how the information sheet and consent form are handed out.
- **Expected sample size** in each case.

Start	Teaching	After grades
Presentation of the study, information sheet and consent	Pre-test and post-test	Perception survey

USUALLY. The requirement for a “balanced and representative” sample does not usually apply in this field: samples are understood to be representative and unbiased.

1.4 · Variables

State which variables will be collected from students or teaching staff: gender, age, year, grades, survey answers, etc.

List only what will be analysed, and make sure it matches what is declared in section 2 and in the information sheet.

1.5 · Data processing

Keep the data protection text included in the form; you may expand it if you consider it necessary.

RULE. If personal data are processed, also complete section 2. A name on a pre/post test is already personal data.

1.6 · Ethics and legal aspects

State explicitly that the study will be conducted in compliance with the **Declaration of Helsinki** and discuss the relevant ethical aspects.

TYPICAL ISSUES IN TEACHING RESEARCH

- **Control groups**: they add a further problem. You must justify why they are appropriate and how they will be managed.
- Genuine voluntariness when the person recruiting is also the person grading.

- Not taking part must have no consequences for grades.

1.7 · Funding body

State who funds the study, even partially: for example, UPV EICE programme or UPV PIME programme. The funder must also appear in the participant information sheet.

NO FUNDING. State that the study is funded with the group's own resources.

Section 2 · Projects with personal data

Complete only if the project processes personal data.

2.1 · Personal data and purpose

State the personal data used in the project and the purpose for which they are used.

2.2 · Source of the data

They usually come from the participant. Sometimes additional data are requested from the ERT; in that case, tick “Other” and specify.

2.3 · Express consent

Normally yes, with reference to the consent form.

2.4 · Anonymisation or pseudonymisation

Describe the process, where applicable. If the data are audio or video recordings, also justify how they are anonymised or pseudonymised.

For example, in a test before and another after a teaching activity, the name may be requested to link both. To avoid storing personal data, each student is assigned a code and the name is removed. If the name–code table is kept, the data are pseudonymised; if it is not needed and is deleted, they are anonymised. If all data are collected anonymously from the outset, simply say so.

2.5 · Tools external to the UPV

Any program in which the personal data are stored and which does not belong to the UPV. This usually refers to survey programs that store data. If so, specify the tool.

2.6 · Third-party access

Normally no third party outside the research team has access. If one does, justify it.

2.7 · Information clause

Participants must be informed about the processing of their data and their rights, and evidence of the information clause must be provided. Normally it is included in the consent form.

2.8 · Data Protection Impact Assessment (DPIA)

For each of the 11 processing activities in the first table, state whether it applies.

- According to the Spanish Data Protection Agency (AEPD), if **two or more criteria** are met a DPIA will be required in most cases, unless the processing is on the list of operations that do not require one (second table, Art. 35(5) GDPR).
- The more criteria are met, the greater the risk.

- If a DPIA is required, consult the **Data Protection Officer** to review the form and carry out the DPIA.

PAY ATTENTION TO CRITERION 4

It covers the special categories of Art. 9(1) GDPR: data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership; genetic data; biometric data for the purpose of uniquely identifying a person; health data; and data concerning sex life or sexual orientation. It also covers data on criminal convictions and offences (Art. 10 GDPR) and data that make it possible to determine financial situation. A survey asking, for example, about students' health or sexual orientation already meets this criterion.

Section 3 · Projects involving recruitment

3.1 and 3.2 · Information sheet and consent

Attach the information sheet that will be given to students or teaching staff before they decide whether to take part, whenever there are interventions (surveys or teaching activities under study), and the informed consent form that participants will sign.

ESSENTIAL. Without these documents the committee cannot issue a report.

Templates are available on the Research Ethics Committee website, although other formats are accepted. The information sheet must explain participation in language suitable for any participant.

3.3 · UPV staff

Normally yes. If not, specify which body is responsible for recruitment.

3.4 · UPV premises

Normally yes. If not, specify the place and attach a letter of commitment from the body that recruits.

3.5 · Insurance

Normally not applicable.

3.6 · Minors or vulnerable groups

Normally not applicable. If applicable, an impact analysis of the processing of personal data is required and, with minors, the signature of the guardian or legal representative on the consent form.

3.7 and 3.8 · Photographs, video and audio

If any kind of recording is made, say so. It must be made very clear in the information sheet and the consent form, and section 2.4 must explain how the recordings are anonymised or pseudonymised.

Section 4 · Social interventions

Teaching research projects with students or teaching staff involve social interventions, so this section is always completed.

4.1 · Questionnaires or surveys

State whether surveys will be used and describe how. The full questionnaires must **always** be attached; otherwise the project cannot be assessed.

4.2 · Interviews or focus groups

Describe the process and attach the structure of the interview and a set of sample questions. Without them the project cannot be assessed.

4.3 · Physiological variables

Normally not applicable. If so, specify the instruments to be used.

4.4 · Rewards

Normally not applicable. If corporate merchandise is given, state it together with its approximate cost and refer to section 6.1. It must appear in the information sheet.

Section 5 · Artificial intelligence

5 · Artificial intelligence

The answer is filled in automatically from the application, but the decision lies with the applicant.

Answer **YES** when the project uses, develops, trains, adapts or integrates an AI system **as part of its own protocol**: data analysis or processing, generating results, interacting with participants or decision support. In that case, **Form 10** must be completed and attached.

Situation	Answer
Spell checker, subtitles, basic transcription, translation or code autocompletion used only as support	NO
Survey of students on how they use AI	NO
An AI system analyses the study data (e.g. open-ended answers)	YES · F10
A chatbot is part of the teaching activity being evaluated	YES · F10

Clinical trials with medical products or devices that use AI are referred to an accredited CEIm (Research Ethics Committee for Medicinal Products).

Section 6 · UPV students

6.1 · Incentives

State and describe any incentives for students to take part; for example, if participation counts towards the grade. If there are incentives, explain in 1.6 how you ensure that those who do not take part are not disadvantaged.

6.2 · Student surveys

Tick when (during the teaching period or after all assessments have been completed and grades released) and in what format (in person or online, anonymous or identified); if there are several instruments, several boxes may be ticked. Attach the full surveys. Additional information must appear in the information sheet (3.1).

Pre/post test	Perception
During teaching · in person with identification (then pseudonymised)	After grades · anonymous online

Giving opinion surveys after grades have been released reduces pressure on students.

6.3 · Interviews or focus groups with students

Tick when and who will conduct them (a researcher who teaches the course or one who does not). Describe the process and attach the structure and a set of sample questions. Additional information must appear in the informed consent form (3.2).

6.4 · Teaching staff

If surveys or interviews are addressed to teaching staff, also provide an information sheet and consent form for them (3.1 and 3.2).

6.5 · Approval of the person responsible for the course

Provide a written approval. If that person is a member of the research team, approval is assumed.

6.6 · Approval of the ERT

Provide a written approval from the ERT (Degree-Awarding Unit). For PIME projects the ERT is understood to have given it already, so the project award letter is sufficient.

6.7 · List of researchers and courses

Filled in automatically with the data from the application: project researchers, courses involved, degree programme and the ERT in which they are taught. You only need to check that it is correct.

Documentation and final checks

Attached documentation

The boxes are ticked automatically from the application according to the documentation provided. Any other relevant documentation is specified by hand in the last field. It is recommended to attach an extended technical report of the project.

IN A TYPICAL PIME WITH SURVEYS

- Extended technical report
- Information sheet and consent form
- Course approval and PIME award letter
- Full questionnaires

Before submitting

- Are the information sheet and consent form attached? Without them there is no report.
- Are the full questionnaires attached and, if there are interviews, their structure and sample questions?
- Are the approvals from the course and the ERT (or the PIME award letter) included?
- Does section 1.6 mention the Declaration of Helsinki?

- If there are personal data, is section 2 complete, including the DPIA table?
- If AI is used in the sense of section 5, is Form 10 attached?
- Are the fields filled in by the application correct?

REMEMBER. The Research Ethics Committee's favourable report must be obtained before data collection begins.