ETHICAL IMPLICATIONS IN SUPERVISED RESEARCH ACTIVITIES (TFG, TFM and Doctoral Thesis)

Supervised research activities (TFG, TFM and Doctoral Thesis) whose methodology requires the student to work directly with human beings (surveys, interviews, tests, measurements, etc.), experimental animals or biological agents and genetically modified organisms (GMOs) and non-anonymised personal data (including medical and biometric data) require a favourable report from the Research Ethics Committee of the Polytechnic University of Cartagena (CEI).

It is the responsibility of the people who supervise these activities to ensure that students learn to carry out research work in a methodologically, ethically and legally correct manner.

As the person ultimately responsible for the activity, the application for ethical evaluation will be made by the person tutoring the work. This information, as well as the relevant documentation, can be found on the following website: https://hrs-researcher.upct.es/actividades/etica- professional/start.

General recommendations for the drafting of supervised research activities

- **Clarity in the description of the study**, explaining the purpose, objectives and ethical relevance of the research to determine the ethical approach to be taken.
- **Ethics and informed consent statement:** It is crucial to include a section addressing the ethical considerations of the study, for example, how informed consent is obtained from participants and how their rights are protected during the research process.
- **Confidentiality and privacy considerations**: Mention how participants' confidentiality will be maintained and how their privacy will be protected at all stages of the study, from data collection to publication of results.
- **Transparency in methodology:** Describe in detail the methodology used in the study, including data collection procedures, participant recruitment, analysis and any other related activities. This helps to ensure the replicability and transparency of the study, which is essential in ethical research.

- Consider a **gender** perspective in activities that use human beings, their data and samples as research material. Sex or gender variables should be considered, both in the methodological design and in the analysis of results. The results of the activity should be presented in a sex-disaggregated form. If this is not the case, scientific justification must be provided.
- In the event that the Tutored Research Activity uses **data provided** by another entity (a clinic, research project, etc.), it is necessary to obtain a transfer document indicating who is providing the data (name, surname and organisation to which it belongs), what is being transferred (type of data, origin and number), to whom it is being transferred (name and surname of the student) and what it is being transferred for (indicating that it is a Tutored Research Activity, and the title).
- **Disclosure of conflicts of interest:** If there is a potential for conflicts of interest that may influence the results of the study, it is important to disclose them in a transparent manner. This includes any funding, institutional affiliations or personal relationships that may bias the research.
- **Ethical analysis of results:** When presenting the results of the study, reflect on the ethical implications of the findings. This involves considering how the results may affect participants, the community and society at large, as well as any ethical actions that may result from them.
- **Ethical and normative references:** Base ethical decisions, on the one hand, on principles recognised in the scientific community. This includes references to professional codes of ethics and institutional ethical guidelines. And, on the other hand, to base them on the various legal regulations that are applicable to the corresponding field of action.
- **Continuous self-assessment:** Throughout the research process, maintain constant reflection on the ethical implications of your actions and decisions. Pay attention to any ethical dilemmas that may arise and address these challenges in a transparent and accountable manner.
- Use **inclusive language**.

Aspects of the tutored activity that are assessed by the Research Ethics Committee

- Social value: What goods or benefits are provided in terms of increased knowledge and/or utility?
  In all research involving the use of human subjects, their samples and/or their data, the mentor should help to identify, define and explain the social value of the project and the need for the use of human subjects, indicating which of the following is relevant to the project

is the current state of play, and what the work will contribute to knowledge, other social goods and student learning.

- Methodological aspects: sample (approximate number and coherent inclusion-exclusion criteria) and its recruitment (who, how, where and when potential participants are contacted), the tools, the variables to be measured and the statistical treatment to be given to the results. All this in order to ensure that the research will be methodologically correct, the first condition for it to be ethically acceptable.

Ethical aspects specific to activities involving human beings, their samples or personal data

- Benefit/risk assessment: It is recommended that research involving human subjects, their biological samples or their personal data with higher than minimal risk should not be performed without direct personal supervision by the guardian. Procedures with higher than minimal risk include:

  — Physical risk: these are those that use invasive techniques such as blood draws.

  — Psychological risk: procedures that may cause the participant to relive traumatic experiences, or subject him/her to significant stress, or invasion of privacy and intimacy.

  — Social risk or sensitive topics such as those with a high level of protection or those that may cause discrimination, social stigmatisation or personal or family harm (political or religious ideology, sexual life, illegal or anti-social activities, alcohol or drug use, mental illness or serious psychological problems, data on active or passive discrimination or harassment, active or passive physical, psychological or sexual abuse or mistreatment).

- Fair sample selection: This implies that the recruitment of study subjects is done for reasons related to the scientific questions included in the research and does not hide other non-scientific interests or motives.
- Protection of vulnerable persons:
  Vulnerable people are: children under eighteen, people with disabilities, people at risk of social exclusion, prisoners, undocumented migrants, victims of crime or violence, people who are ill or in other conditions of distress.
  For example, in a supervised activity involving minors in educational institutions, it is necessary to obtain the appropriate

authorisations for centres outside the UPCT, in addition to the consent of both parents or, where appropriate, of those exercising such a function, the consent of the minors and, sometimes, the specific collaboration of the teaching staff or staff of the centre.

Requires **direct face-to-face guardianship** by the guardian.

- Information and consent: information to be received by the participant, ascertaining the participant's understanding of the information and obtaining consent. Informed consent is the procedure by which it is ensured that the subject has voluntarily expressed his/her intention to participate in research, after having understood the information given to him/her about the aims of the research, the benefits, discomforts, possible risks and alternatives, his/her rights and responsibilities.

  You can find models from these documents at at https://uitt.upct.es/oficina-virtual/solicitud-de-evaluacion-etica/inicio.

  Recruitment may NOT commence without a Favourable Report from the REC.
- Protection of personal data: whenever personal data are processed in the activity, the person in charge of the activity must take into account the requirements of personal data protection regulations.

  You can consult the Basic Guide for researchers on personal data protection with the support of the UPCT's Data Protection Delegate (DPD) who can be contacted by e-mail: dpd@upct.es.

Specific ethical aspects of activities with experimental animals: the supervised activity must necessarily be carried out under the auspices of a research project that has been reported favourably by the REC of the UPCT.

Specific ethical aspects of activities involving the manipulation of biological agents and GMOs: the supervised activity must necessarily be carried out under the auspices of a research project that has been favourably reported by the UPCT's REC.

Other sources to consult:

Ethics Committee for Research on Human Subjects, their data and samples (CEISH-UPV/EHU).

Spanish Research Ethics Committee.

European Code of Conduct for Research Integrity.

Code of Ethics of the Polytechnic University of Cartagena.

Code of Good Research Practices of the Polytechnic University of Cartagena.