RECOMMENDATIONS AND INSTRUCTIONS of the **Standing Committee of the Research Ethics Committee of Universidad San Pablo-CEU** on the development of **RESEARCH WORKS** carried out in/presented at USP-CEU.

1. GENERAL THOUGHTS:

1) The main function of the Research Ethics Committee (REC) of the Institution is to promote and ensure the protection of people's fundamental rights, their personal data, the proper treatment of animals used as experimental models, the environment and the protection of workers.
2) If you wish to apply for a research project, it is common for research funding bodies to require a favourable report from the REC.
3) In case the results of the research work are meant to be published, difficulties may arise if the editors of the publication require the approval of the project by an REC and it has not been approved.
4) The main researchers of the projects (MRs), directors of theses, and of teaching research work (Undergraduate research works (TIG), Bachelor's Degree Dissertations (TFG) and Master's Degree Final Projects (TFM)), are responsible for submitting applications for evaluation to the REC.
5) Applications must be sent as far in advance as possible, as the designs of the studies are evaluated before the experimental phase, sample collection, personal data collection, surveys, recordings, etc., begins. The REC cannot issue favourable reports on studies that have already passed this phase or have already been completed.
6) All researchers involved must be listed in the studies.
7) Research projects, theses and teaching research projects that include tasks that concern more than one subcommittee of the committee must have a favourable report from all the subcommittees that are to evaluate them in order to be initiated.
8) The REC promotes ethical behaviour in research and ensures compliance with Act 14/2007, of 3 July, on Biomedical Research and Organic Act 3/2018, of 5 December, on Personal Data Protection and guarantee of digital rights, but the main researcher, tutor/director of the research studies, is ultimately responsible for complying with the regulations and ensuring that they are complied with.

2. TYPES of Research Works that MUST BE EVALUATED BY CEI-USP-CEU

Research Projects, Doctoral Thesis Projects, TFG/TFM and TIGs involving research must be evaluated by a Research Ethics Committee:

- The use of biological samples of human origin or data from humans, in studies in Experimental Sciences, Health Sciences and Life Sciences.
- Studies involving human subjects, use of their personal data, in studies in the Social Sciences and Humanities.
- Animal testing procedures.
- Use of biological, chemical, radioactive agents or genetically modified organisms or organisms that affect the environment, humans or animals.

2.1: DO NOT REQUIRE ERC'S AUTHORISATION

Experimental, Health and Life Sciences Studies:

Observational (non-drug) studies that do not involve interventions or the use of biological samples of human origin, and that only use clinical records or other anonymous or anonymised personal data do not require ERC's approval.

Social Sciences and Humanities Studies:

When anonymous data or anonymised databases are used, it is possible to carry out studies with such databases. In such studies, the ethical principle of autonomy is not breached.

However, as it has already been mentioned, journals usually request this opinion as a quality criterion for publication, so it is advisable that they also have a favourable report from the corresponding REC (this would be an administrative procedure).

3. THOUGHTS WHEN CHOOSING THE TEACHING RESEARCH WORK'S SUBJECT:

3.1.- If the director/tutor decides to carry out a research project (TIG, TFG, TFM) that includes studies listed in section 2 of this document, before starting, it is optimal to:

3.2.1. That his/her approach is within a research study previously approved by a Research Ethics Committee. In these cases, provided that the parameters of the already approved study are maintained, the REC will simply ratify the approval of the design of the TIG/TFG/TFM, after a simple administrative procedure.

3.2.2. Designing an educational research project that involves only the use of samples or data already collected for another function. Although such work has to be evaluated by the committee, it is a significant reduction of problems from the point of view of research ethics. In human studies, depending on the case, further informed consent from the source subject will have to be sought or the authorisation of the person responsible for the custody of the samples or data will suffice.

3.2.3. A 'TIG/TFGs/TFMs line of work' can be proposed in a similar way to the lines of research. This should be done directly by the tutor/director with the idea of proposing similarly designed work to students. This would involve a single assessment application for multiple papers, which would be similarly designed. There would be a first evaluation by the committee to ensure authorisation of access to samples, data, confidentiality, etc. From then on, all the TIG/TFGs and TFMs associated with the line would be processed almost automatically simply by indicating the change in the type of data to be accessed, using the same files, authorisations and methodology.

NECESSARY DOCUMENTS FOR ERC'S ASSESSMENT

The necessary documents, depending of the type of study, that must be filled in and submitted to the ERC's Technical Secretariat investigacion@ceu.es (OTRI), can be found in: https://www.uspceu.com/investigacion/comites-comisiones

Summary:

- The main researchers and directors/tutors are responsible for sending, from their CEU e-mail address, the evaluation applications with their name, location and signature, (in addition, the student's name in the case of Theses/TIG/TFG/TFM) and other relevant documents to the Technical Secretariat of the Ethics Committee and should do so as early as possible, since once it has been verified that the documentation received is complete and in the correct format, it is distributed to different evaluation subcommittees. If the application is sent late, REC's evaluation process, which sometimes involves requesting new documentation, corrections or clarifications of the report received to those responsible for the studies, may mean a delay in the start of the work and therefore for its subsequent presentation and defence (see evaluation process in Fig. 1).
- The ERC assesses study designs before starting the experimental phase, sample collection, survey data collection etc... ERC cannot issue favourable reports on studies that have already passed this phase or have already been completed.

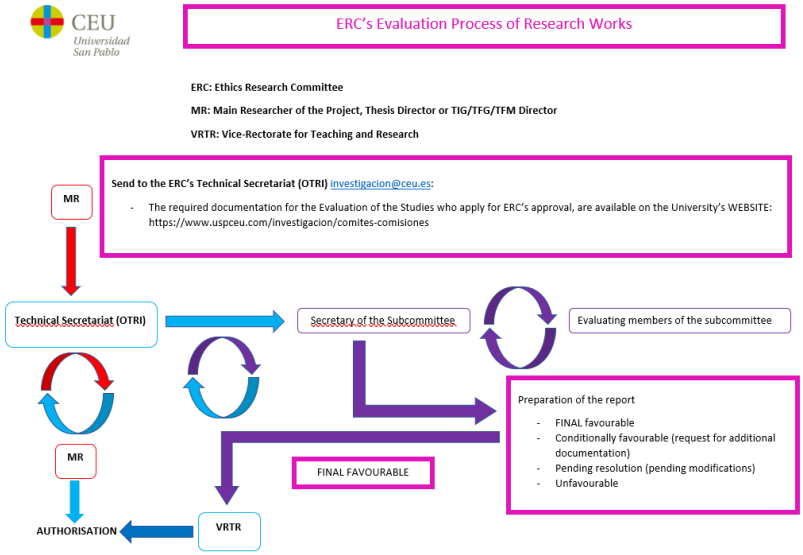

Figure 1: ERC's Evaluation Process

USP-CEU ERC'S SUBCOMMITTEES

- **Subcomittee on Human Samples and Clinical and Human Trials:** evaluates research using biological samples of human origin or data from humans, in Experimental and Health Sciences and Life Sciences studies.

- **Subcommittee on Social Sciences and Humanities:** evaluates studies involving human subjects, use of their personal data, in Social Sciences and Humanities studies.

Necessary documents:

a) **Always**: Application (including a report on the design of the work).
b) **Always:** Confidentiality commitment.
c) **Only if necessary**, attach the Model Subject/Patient Information and Informed Consent Form.
d) It depends, whether data are anonymised or pseudonymised)

In general terms, the use of anonymised data or anonymisation of the data of the participants should be pursued, except where the characteristics of the study require another duly justified procedure (this also applies to biological samples).

Anonymous data: data recorded without a link to an identified or identifiable person: It is not necessary to send the subject/patient information and the informed consent form to the Committee. For anonymous surveys delivered on paper or sent via the internet, it is recommended that the following be included in the wording: The purpose of this survey is '.....'. 'If you start the survey, it means that you agree to participate and that you want to answer the questions in this survey.'

ANONYMISED DATA: Total break in the chain of identification of individuals (also applicable to the biological sample: '**Irreversible dissociation**': data that cannot be associated with an identified or identifiable person because the link with any information identifying the subject has been destroyed, or because such association requires an unreasonable effort, meaning the use of a disproportionate amount of time, expense and labour. The subject/patient information and informed consent form does not need to be sent to the Committee.)

PSEUDOANONYMISED DATA: processing of personal data without the data subject's identification data, but without removing the link between the data which makes it possible to identify the data subject. '**Reversible dissociation**'. An example would be the replacement of the names of the study subjects by pseudonyms, by a code or by a numerical identifier. (If necessary, send to the Committee the model of information to the subject/patient and the informed consent, which is signed by the study subject).

Animal Welfare Subcommittee: Evaluates studies involving animal testing procedures.

Necessary Documents: Application; Annex X; Non-Technical Summary; Technical Report of the Project to be carried out.

Subcommittee on Biosafety and Environmental Safety: Evaluates studies involving the use of biological, chemical, radioactive agents or genetically modified organisms or affecting the environment, humans or animals.

Necessary Documents: Application; Project report; Safety data sheet of the agent; List of workers who will handle the agent and available protective equipment (PPE).

LEGISLATION OF APPLICATION

RESEARCH ETHICS COMMITTEE REGULATIONS: **https://www.uspceu.com/investigacion/documentacion:**