**"Application for Experimental TFG (end-of-degree project)/TFM (end-of-master’s project) Evaluation" by the Subcommittee for Human Samples and Clinical Trials on Humans**

 **Reference**

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| --- |
| **TFG/TFM title:** |

**Tutor/Director data:**

Name and surname:

Department/Faculty:  Address: (building, room, etc.,):

Telephone number (ext):       email:

Signature

 Madrid, ....................           , 201.......

|  |
| --- |
|  Type of research work: If already assigned, **student's name and surname:** |

 **Is this study part of a Research Project which has already received a Favourable Report from the CEU-USP Ethics Committee, another Research Ethics Committee or CEIC?**

* If the answer is **yes**, please specify the Authorization Number in said report:
* If the answer is **no**, please continue to fill in this document.

# Specify whether the proposal includes any of the following aspects

**A.**- *Clinical experimental research with human beings* YES NO

***B.****- Use of human tissues, biological samples, embryonic or foetal tissues* YESNO

***C.****- Use of human tissues, biological samples, embryonic or foetal tissues* YES NO

***from banks of samples or tissues***

**D.**- Observational research with humans or use of personal dataYES NO

**If the answer is YES in any of these sections, the following documents must be attached to the project report:**

* Favourable report from the Clinical Research Ethics Committee (A)
* or the patient information and informed consent form (B, D)
* or the consent for transfer authorisation from the person in charge of the samples custody, for the specific project (e.g. Biobank Director or Collaboration Agreement with USP-CEU) (C)
* **And IN ALL CASES**, Confidentiality agreement from **each of the members of the research team**. (A-D)

**Additional information (always fill in)**

* Participating researchers:
* Funding entity (if applicable):
* Participating private or public institutions:
* Location (centre, city) where the research project will be carried out:
* Research starting date:

**Reference**:

**BRIEF TFG/TFM DESCRIPTIVE REPORT: All sections and sub-sections bellow must be included**

 **(Must be only 1-2 pages)**

**1.- Title:**

**2.- Objective/s:**

**2.1.- Benefits from the research project:**

**3.-Type of research: (**Experimental or observational. Transversal, longitudinal, etc...)

**4.- Materials and Methods:**

**4.1.- Population under study. Subjects** (age, race, gender). **Criteria for inclusion and exclusion of subjects. Tissues, types of biological samples, cell cultures, etc...**

**4.2.- Size of the sample** (number of subjects, number of samples, etc.…).

**4.3.- Methodology:** Extraction method for the biological samples, tissues, name of the biobank (if applicable). Laboratory experiments and procedures. Where appropriate, model survey, data collection sheet. Where appropriate, pre-validation of the selected intervention.

**Indicate (as appropriate):** (check your selected option)

* Genetic test will be run  YES NO
* Genetic data will be used YES NO
* The process is carried out using anonymous data: YES NO **(if the answer is YES, NO informed consent and information document need to be attached)**
* The research is carried out with anonymized data YES NO (**if the answer is YES, and the research will be carried out with duly anonymized data without any possibility of re-identification of the individuals: NO informed consent and information document need to be attached. Otherwise, the subject's informed consent must be attached (or a favourable statement from the Clinical Research Ethics Committee or another Ethics Committee)**
* Is the conservation of the biological sample ensured without any interruption of the cold chain? YES NO

**4.4. Potential risks of the research project:** Applies to any undesirable or involuntary experience that may affect the subject during the research.

**4.5. Statistical analysis of the results and significance level.**

**4.6. Specific participation of the student in the research project:**

**4.7. Approximate date for the reading of the paper (month/year)**

**5.- Relevant literature (3-5 references)**

**Reference**

**Experimental TFG/TFM Project title:**

**ATTACHED to the application: *(mark with an X):***

1.- BRIEF DESCRIPTIVE REPORT OF THE WORK

2.- If applicable: FAVOURABLE REPORT FROM THE CLINICAL RESEARCH ETHICS COMMITTEE

3.- If applicable: CONSENT FOR TRANSFER AUTHORISATION, FROM THE PERSON IN CHARGE

OF THE SAMPLES CUSTODY, FOR THE SPECIFIC PROJECT (e.g. Biobank Director)

4.- [PATIENT INFORMATION AND INFORMED CONSENT FORM for TFG/TFM](http://www.uspceu.com/es/investigacion/documentacion-y-descargas/_documents/Informacion%20al%20paciente%20y%20consentimiento%20informado_11-07-2016.docx)

5.- [CONFIDENCIALITY AGREEMENT](http://www.uspceu.com/es/investigacion/documentacion-y-descargas/_documents/Compromiso%20de%20confidencialidad%20%28proyectos%20investigaci%C3%B3n%29_%2011-07-2016.docx). (Each participating researcher)

- Documents: http://www.uspceu.com/investigacion/documentacion. RESEARCH ETHICS COMMITTEE. Subcommittee for Human Samples and Clinical Trials on Humans

6.- The director/tutor and the student agree to comply with the regulations governing this research project:

Documents must be sent to the Technical Secretary of the Ethics Committee in Research (OTRI): irene.crespoborrego@ceu.es . 913724700 (ext. 4731) who will forward it to the Subcommittee for evaluation.

Applicable regulations:

* EUROPEAN PARLIAMENT AND COUNCIL REGULATION (EU) 2016/679 of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
* Royal Decree 1090/2015 of 4 December, regulating clinical trials with medication, Research Ethics Committees and the Spanish Register of Chemical Studies
* Royal Decree 1716/2011 of 18 November establishing the basic requirements for the authorisation and operation of biobanks for the purposes of biomedical research and the treatment of human origin biological samples, and regulating the operation and organisation of the National Register of Biobanks for Biomedical Research.
* Law 14/2007 of 3 July on Biomedical Research.
* Law 41/2002 regulating patient autonomy and rights and obligations in the area of clinical information and documents.