**Request for Research Project Evaluation**

 Authorization

In accordance with Articles 2 and 5 of the San Pablo CEU University Ethics Committee Regulations, researchers who request this Committee's evaluation must submit this form duly filled in to the Committee's Secretariat, together with the requested documents.

|  |
| --- |
| Title of the research project:  |

# Lead Researcher Data

 Name and last name:

 Department:

 Address:

 Phone number:

 Fax:

 email:

 Signature

 Madrid, ....................           , 20.......

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Purpose of the certificate:**

|  |  |
| --- | --- |
| Financially supported project  |  |

|  |  |
| --- | --- |
| Project with no funding  |  |

|  |  |
| --- | --- |
| Teaching: | **Student’s name and last name:**  |
|  | University Degree |  |

|  |  |  |
| --- | --- | --- |
|  | Masters Program |  |

|  |  |  |
| --- | --- | --- |
|  | PhD |  |

 |

# 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* YES NO

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 data* YES NO

 **A-D sections. When the answer is YES, please attach:**

* Favourable report from the Clinical Research Ethics Committee
* or the patient information form and an informed consent
* or the consent from the person with custody over the samples (e.g. Director of the biobank or Collaboration Agreement).
* Confidentiality agreement from each of the members in the research team
* **ATTACH REPORT OF THE PROJECT SUBMITTED FOR EVALUATION** (free template).

**The project report must include:**

1.- Title of the research project:

2.- Objective/s:

 2.1.- Potential benefits and risks of the project (Applies to any undesirable or involuntary experience that may affect the subject during the research process).

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...

In this section, please clarify:

* If a genetic study is to be carried out
* If the genetic data will be used
* If the project is to be carried out with anonymous data: NO informed consent and information document need to be attached.
* If the project will be carried out with duly anonymized data without any possible means of re-identifying 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).
* Specify whether the conservation of the biological sample is ensured without any interruption of the cold chain.

 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 tests and procedures. Where appropriate, model survey, data collection sheet. Where appropriate, pre-validation of the selected intervention.

 4.4. Statistical analysis of the results and significance level.

 4.5. Timetable and specific participation of each researcher

5.- Relevant literature (5 references)

E.- *Animal testing* YES NO

If the answer is YES, please continue to the Biosafety section

F.- *Use of biological agents which may present a risk for human or animal health* YES NO

*or for plants*

If the answer is YES, please continue to the Biosafety section

G.- *Use of genetically modified organisms (GMOs)* YES NO

If the answer is YES, please continue to the Biosafety section

If the answer is NO, this form has been fully completed

# Biosafety

**1.- In scenario E**, you must attach the official application form for experimental projects with animals and, in addition, in the case of using infectious biological material, you must attach a report containing this information:

a) infectious agent and its classification according to its hazardous nature (Directive 2000/54/EC and RD 664/1997)

* *group 1 biological agent*: a biological agent that is not very likely to cause disease in humans.
* *group 2 biological agent*: a pathogen that may cause disease in humans or may be dangerous for workers; effective prophylaxis or treatment is usually available.
* *group 3 biological agent:* a pathogen that can cause severe disease in humans and presents a significant hazard for workers; there is a risk that it may spread to the community but effective prophylaxis or treatment is usually available
* *group 4 biological agent*: a pathogen that can cause severe disease in humans and may be highly dangerous for workers; there is a high likelihood of its spread to the community; generally no effective prophylaxis or treatment is available.

b) biosafety level required for its use with animals (see classification of biosafety levels in section 2.3).

In addition, in cases of inoculation of compounds identified with radioisotopes, a report from the person in charge of Radioprotection at the Centre verifying the procedure must also be attached.

**2.- In scenario F**

**2.1. Use of biological agents which present a risk for human health**: a report should be attached containing

2.1. 1. infectious agent and its classification according to its hazardous nature (Directive 2000/54/EC and RD 664/1997; both available in PDF format)

* *group 1 biological agent*: a biological agent that is not very likely to cause disease in humans.
* *group 2 biological agent*: a pathogen that may cause disease in humans or may be dangerous for workers; effective prophylaxis or treatment is usually available.
* *group 3 biological agent:* a pathogen that can cause severe disease in humans and presents a significant hazard for workers; there is a risk that it may spread to the community but effective prophylaxis or treatment is usually available
* *group 4 biological agent*: a pathogen that can cause severe disease in humans and may be highly dangerous for workers; there is a high likelihood of its spread to the community; generally, no effective prophylaxis or treatment is available.

2.1. 2. biosafety level required for its use with animals (see classification of biosafety levels in section 2.3).

**2.2.** **Use of biological agents which present a risk for animal health**: a report should be attached containing

2.2.1 infectious agent and whether it causes any disease compulsorily notifiable to the OIE (World Organisation for Animal Health). Visit the website describing the Terrestrial Animal Health Code (http://www.oie.int/esp/normes/mcode/E\_summry.htm)

2.2. 2. biosafety level required for its use with animals (see classification of biosafety levels in section 2.3, but applied to animal health).

**2.3.** Use of biological agents with risk for plants: state the required biosafety level according to the following classification. In any case, it is the responsibility of the investigator to choose any given biosafety level.

* BSL1-P: suitable for work with unmodified or genetically modified organisms or micro-organisms (GMOs) which:
	+ cannot survive outside research facilities (laboratories, controlled growth chambers, greenhouses, etc.) or cannot be disseminated in the wild
	+ even if they can spread, they do not have any harmful effects on agricultural crops or natural ecosystems
* BSL2-P: suitable for work with unmodified or genetically modified organisms or micro-organisms (GMOs) which:
	+ even when they can survive and spread outside the research facilities, have a negligible or minimal impact on agricultural crops or natural ecosystems.
	+ are native to our country, infectious or potentially infectious but with known and controllable effects in terms of plant health.
	+ come from other countries but are not capable of causing significant health problems in agricultural crops or natural ecosystems.
* BSL3-P: suitable for work with unmodified or genetically modified organisms or micro-organisms (GMOs) which:
	+ come from other countries and could cause significant health problems in agricultural crops or natural ecosystems
	+ organisms or micro-organisms with a genetic modification affecting genes involved in the production of toxins affecting vertebrates.

In addition, you should briefly clarify the following aspects:

1. What is the origin of the biological agent used?

2. What transportation methods are used for the biological agent?

3. What is the procedure for final inactivation of the biological agent?

4. What is the procedure for disposal of the inoculated plants?

**3. In scenario G**

the researcher must evaluate the risk level of the GMO in accordance with the legislation in force (RD 178/2004) and in accordance with the following table:

- Type 1: zero or negligible risk

- Type 2: low risk

- Type 3: moderate risk

- Type 4: high risk

The facilities in which the research is carried out must meet the biosafety characteristics described as type BSL-1, BSL-2 or BSL-3 (see previous section).

Important: for any of the previous scenarios, San Pablo CEU University does not consider the handling of pathogens or GMOs with risk level 3 or 4 and for which BSL-3 and BSL-4 level facilities would be accordingly necessary.