**FORM 1**

**Statement confirming the use of experimentation involving humans or biological samples of human origin.**

**I,**

The undersigned, principal investigator of the project \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ,

The undersigned, doctoral student submitting the thesis \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ,

**state that:**

The project DOES include experimentation involving humans.

The project WILL use samples of human origin.

**Name and surname(s):**

**Department / Unit:**

**Postal address:**

**Telephone:**

**Email address:**

**Signature and date:**

***If applicable:***

**Name and surname(s) of thesis supervisor:**

**Department/unit:**

**Postal address:**

**Telephone:**

**Email address:**

**Signature and date:**

**Documents to be submitted:**

A) If the project proposal has already received a **favourable** report from the Research Ethics Committee of the Faculty/School/other where the experimentation will take place or that will provide the samples, please submit a scanned copy of this report.

B) In all other cases, please submit the following:

* + - 1. A brief scientific and ethical rationale for the research, including a description of the anticipated impact on participating individuals and of the benefits and risks envisaged as a result of the research.

1. The detailed information that will be supplied to volunteers involved in testing (the model of the project information document, the consent form that will be used, and the procedure for obtaining consent).

*A model informed consent form is provided on the CBUB web page:*

[*www.ub.edu/recerca/comissiobioetica.htm*](http://www.ub.edu/recerca/comissiobioetica.htm)

If the project involves the use of biological samples of human origin that are deposited in a biobank or that are part of a collection of samples for the purposes of biomedical research and preserved outside the organizational sphere of a biobank, you must also submit a copy of the request form releasing the samples to a specific researcher (*naming the researcher*) and for a specific project (*naming the project*).

**In all cases, submit the following:**

1. Statement of compliance indicating that the confidentiality of the data that may be obtained in the project will be scrupulously observed. Any project results that may affect or be of interest to participating individuals or groups must be communicated to them.
2. Statement of compliance indicating that the samples will not be used for or ceded for use in other studies. In the latter case, researchers must first obtain written approval from the Ethics Committee.
3. Statement of compliance by the principal investigator of the project and/or the doctoral thesis supervisor indicating the intention to adhere to the notifications of the Ethics Committee on student participation in research projects (*only in applicable cases*) and on potential ethical issues in scientific publications. These notifications can be found on the Ethics Committee’s web page: [www.ub.edu/recerca/comissiobioetica.htm](http://www.ub.edu/recerca/comissiobioetica.htm)
4. Scanned copy of the favourable report issued by the Animal Experimentation Ethics Committee (CEEA), if the project involves animal experimentation.

* Details of any monetary or other compensation anticipated in the project either for the principal investigator (or research team) or for the participating individuals or groups. If no payments are envisaged, please indicate here.
* Details of insurance coverage for volunteers, if applicable.

1. Any other relevant information.

**This statement must be attached to the research project application submitted to the Research Management office.**