UNIVERSITAT DE BARCELONA

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FORM 1

INFORMATION AND NECESSARY DOCUMENTS TO REQUEST THE CBUB ASSESSMENT OF RESEARCH PROJECTS INVOLVING EXPERIMENTS WITH HUMAN SUBJECTS OR THE USE OF BIOLOGICAL SAMPLES OF HUMAN ORIGIN (JUNE 2023)

In this document, the Bioethics Committee of the University of Barcelona (CBUB) lists the documents and issues to be taken into account to request the assessment of a research project, master's degree final project, bachelor's degree final project[1] or doctoral thesis involving experiments with human subjects or the use of biological samples of human origin.

1. Declaration of experiments with human subjects or the use of biological samples of human origin in research projects, duly completed and signed (Annex 1).

2. Project report/complete research protocol (maximum length of 25 pages) or, where applicable, the doctoral research project approved by the Doctoral Studies Committee (see the Regulations governing doctoral studies at the UB) and, if necessary, any updates endorsed by the supervisor. It must include the bioethical justification for the project, including a description of the following aspects:

2.1. The expected impact on the participants.

2.2. The expected benefits and risks of the research.

2.3. If it is considered that any outcome of the project might affect or be of interest to the participating individuals or groups, the applicant must explain in detail how the research team will manage this issue.

2.4. The detailed information to be received by the volunteer test subjects. For research projects or doctoral theses involving the participation of minors, in addition to the signature of the minors' parents or legal guardians, the consent form must explicitly record the minors' own assent. (Remember that minors must be previously informed of the project's characteristics, procedures and aim, in keeping with gradual standards regarding their capacity to understand.) The research team will ensure that the minor's well-being and comfort are taken into account throughout the experimental process, paying special attention to his or her possible rejection or refusal to continue participating in the project.

2.5. If participation of UB students is expected, the CBUB's statement on student participation in research projects should be taken into account.

2.6. If the project provides for financial or other forms of compensation, both for the principal investigator and for the research team and/or the participating individuals or groups, this must be specified. If no such compensation is planned, this must be indicated.

2.7. Where applicable, specify the insurance policy taken out on behalf of the participating volunteers.

Remember to attach the following to your application:

- **Model participant information sheet/document** (Annex VII A of the Guidelines for the correct preparation of a model patient information sheet and informed consent form, version 27 March 2023 or annex 2).

1. That is, bachelor's degree final projects involving the implementation of an experimental study with human subjects or that use biological samples of human origin under the supervision of a UB researcher.

- **Model informed consent/assent form** to be used, as well as the procedure to be used to obtain the latter (Annex 3).
- Data processing and protection details (see point 4).

3. Specific authorizations and declarations

3.1. In the case of cadaveric specimens, authorization of the dissection room/service director.

3.2. In the case of biological samples (tissues, cells, fluids, etc.) in a clinical setting, authorization of the laboratory or biobank or a favourable report from the Drug Research Ethics Committee (CEIC, CEIm) of the centre where the experiment will be conducted or that will supply the samples.

3.3. If the project plans to use biological samples that are part of a sample collection for biomedical research purposes held anywhere other than a biobank, you should attach a copy of the application form for the samples' transfer to a specific researcher (cite name) and for a specific project (cite title).

3.4. If experiments with non-human animal subjects will also be performed, attach the favourable report of the Animal Experimentation Ethics Committee (CEEA).

4. Data management plan

4.1. If the research project, master's degree final project, bachelor's degree final project or doctoral thesis requires data processing, see the information on the research data management website and attach a data management plan. In case of calls for funding requiring a data management plan where none is available, contact the CBUB.

5. Personal data processing and protection

5.1. If the research project, master's degree final project, bachelor's degree final project or doctoral thesis requires personal data processing[2], see the Guide for Researchers at the University of Barcelona on the Protection of Personal Data. You can process personal data only when the purposes of the processing can't be fulfilled by the processing of anonymized or anonymous data.

5.2. If personal data will be used, the participant information sheet/document must include certain information regarding the processing of those data. See section 5.1 of the aforementioned Guide and the model right to information notices[3] published with it (there are

2. Personal data: any information relating to an identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier, such as a name, an identification number, location data or an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

3. With regard to doctoral theses, these model notices can be used when the student has a predoctoral contract or when the personal data processing to be performed will take place within the framework of a funded research project. For all other doctoral thesis cases and for master's and bachelor's degree final projects, the guidelines published by the Spanish Data Protection Agency must be followed.

four model notices, depending on whether or not the experiment involves special categories of data[4] or international data transfers).[5]

5.3. As far as possible, pseudonymized personal data should be used.[6] In this case, it must be indicated on the participant information sheet.

5.4. In the case of research projects and doctoral theses based on surveys, questionnaires and similar, use the Forms program available on the cloud that the University of Barcelona has contracted from Microsoft. Other free software programs that store information on UB servers will also be accepted.

5.5. In any case, programs contracted by the University of Barcelona must be used rather than individually contracted ones.

5.6. If the data are personal, attach a self-assessment of the need for a data protection impact assessment in accordance with Annex 4.

6. Declaration of specific pledges

In this declaration, the principal investigator of the project or the doctoral student and their thesis supervisor agree:

6.1. To scrupulously protect any data that might be obtained in this project/thesis

6.2. Not to transfer or use the samples for other different studies In this case, the researchers must first request the corresponding report from the CBUB.

6.3. That the people involved in the content of the doctoral thesis, bachelor's degree final project or master's degree final project will not commit plagiarism, in keeping with the provisions of the UB's Code of Good Research Practices.

In case of using anonymized or pseudonymized data:

6.4 Express commitment to confidentiality and to refrain from carrying out any re-identification activities.

6.5 Commitment to adopt specific security measures to prevent re-identification and unauthorized third-party access.

All documents must be sent to the UB Bioethics Committee at the email address cbub@ub.edu.

4. Special categories of data: personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership; the processing of genetic or biometric data for the purpose of uniquely identifying a natural person; data concerning health or data concerning a natural person's sex life or sexual orientation.

5. International data transfer: communication of personal data outside the European Economic Area (EU Member States, Iceland, Norway and Liechtenstein).

6. Pseudonymized data: data that can no longer be attributed to a specific person without the use of additional information, provided that such additional information is kept separately and is subject to technical and organizational measures.

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RIGHT TO INFORMATION PERTAINING TO THE PROCESSING OF PERSONAL DATA

Data controller	General Secretary's Office of the University of Barcelona Gran Via de les Corts Catalanes, 585, 08007 Barcelona secretaria.general@ub.edu
Purpose of the processing	To manage the activity of the Bioethics Committee of the University of Barcelona
Lawful basis	Performance of a task carried out in the public interest (Spanish Organic Law 6/2001, of 21 December, on Universities, and Catalan Law 1/2003, of 19 February, on Catalan Universities).
Data storage period	Data are stored for as long as needed to fulfil the purpose for which they are collected and determine any possible liability that might arise therefrom.
Recipients	The recipients are the University of Barcelona and the data processors, where applicable. Data will not be transferred to third parties except where required by law.
Rights of the individual	You may access your personal data and exercise your rights of rectification, erasure, objection, portability or restriction by writing to the General Secretary's Office of the University of Barcelona by post (Gran Via de les Corts Catalanes, 585, 08007 Barcelona) or e-mail (secretaria.general@ub.edu). You must attach a photocopy of your Spanish ID card (DNI) or another valid ID document.
Data protection officer	If you think that your rights have not been adequately respected, you can lodge a complaint with the UB's data protection officer by post (Gran Via de les Corts Catalanes, 585, 08007 Barcelona) or e-mail (protecciodedades@ub.edu).
Supervisory authority	You may also lodge a complaint with the Catalan Data Protection Authority.

ANNEX 1

DECLARATION OF EXPERIMENTS WITH HUMAN SUBJECTS OR THE USE OF BIOLOGICAL SAMPLES OF HUMAN ORIGIN IN RESEARCH PROJECTS

Name and surname(s): .....

Doctoral programme (if applicable): .....

Section and department (if applicable): .....

Postal address (campus, street name and number, post code and town/city): .....

.....

Telephone no.: .....

Email: .....

Estimated date of data collection for the research project, master's degree final project, bachelor's degree final project or doctoral thesis:* .....

.....

Acting as:

☐ principal investigator of the project titled

.....

☐ doctoral student submitting the thesis titled .....

.....

☐ author of the bachelor's/master's degree final project titled

.....

In the case of doctoral thesis, indicate in which situation from the following it falls within:

☐ UB predoctoral contract

☐ Without predoctoral contract but framed within a UB-funded research project (project title: .....)

☐ Without predoctoral contract but framed within a UB research project of institutional interest (project title: .....)

☐ None of the above

By signing this document, I declare:

1. That the research entails:

   ☐experimentation with humans
   ☐use of samples of human origin
   ☐ use of animals

*The CBUB will not evaluate applications for research projects, bachelor's degree final project, master's degree final projects or doctoral theses for which the collection of data has already begun. For more information, contact cbub@ub.edu.

2. That the recorded data and submitted documents are reliable.

3. That I have read the right to information notice about the processing of my personal data included on the last page of Form 1.

Date and signature: .....

ONLY WHEN APPLICABLE

Name and surname(s) of the final project or thesis supervisor: .....

Doctoral programme (if applicable): .....

Section and department (if applicable): .....

Postal address (campus, street name and number, post code and town/city): .....

.....

Telephone no.: .....

Email: .....

Date and signature: .....

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ANNEX 2

MODEL INFORMATION SHEET/DOCUMENT FOR THE PARTICIPANT OR PATIENT (FOR REFERENCE PURPOSES)

Study title: .....

Code: .....

Sponsor: .....

Principal investigator: .....

Centre: .....

1. Introduction

   Example: *We are writing to inform you about a research study in which you are invited to participate. The study has received a favourable report from the Drug Research Ethics Committee and/or the Bioethics Committee of the University of Barcelona. Our aim is to provide you with sufficient and accurate information so that you can decide whether or not to participate in this study. To this end, please read this information sheet carefully and do not hesitate to contact us should you have any doubts.)*

2. Voluntary participation

   Example: You should know that your participation in this study is voluntary and that you may decide NOT to participate. *If you do decide to participate, you can change your mind and withdraw your consent at any time, without prejudice.*

3. Study aim

4. Description of the study targeted at participants. This must include, where applicable: total number of participating subjects, medicines/intervention, number of treatment groups, group assignment procedure, whether data masking will be used and, if so, what kind, and whether there is a placebo.

5. Duration of the study, number of visits or frequency thereof (available resources, commutes, access).

6. Risks and inconveniences of participating in the study.

7. Possible benefits

8. How and where the study results will be disseminated.

9. Contact information in case of doubts.

10. Warnings for specific cases: pregnancy, children, adolescents, people with chronic diseases, polypharmacy, etc.

    Where applicable: *In case of pregnancy occurring during your participation in the study, tell your doctor immediately to receive the appropriate care.*

11. Expenses and financial compensation

    Where applicable: *The study sponsor is responsible for arranging the funding. You will not have to pay for the medicines/treatments or study-specific tests. Your participation in the study will not entail any expense in addition to the usual clinical practice and you will be reimbursed for any extraordinary expenses (food, transport) incurred.*

12. Insurance

13. Personal data protection and management
14. Other relevant information

ANNEX 3

MODEL INFORMED CONSENT FORM (FOR REFERENCE PURPOSES)

Research project title: .....

(The volunteer has to read and answer the following questions carefully.)
(For Yes/No questions, circle the answer you consider correct.)

Have you read all the information provided to you about this project?	Yes / No
Have you had the chance to ask and discuss any questions you might have about the project?	Yes / No
Have you received enough information about this project?	Yes / No
Have you received satisfactory answers to all your questions?	Yes / No
Which researcher informed you about this project? *(name and surname(s)*)	
.....	
Have you understood that you can withdraw from this project without prejudice?	Yes / No
• At any time	Yes / No
• Without giving any reason	Yes / No
Have you understood the possible risks associated with your participation in this project?	Yes / No
Do you agree to participate?	Yes / No
Do you consent to the processing of your personal data?[1]	Yes / No
Will you receive any type of compensation for participating?	Yes / No
Do you authorize the person for whom you are responsible to participate in the project? *(only when applicable)*	Yes / No

.....

(Any other items that should be included, in accordance with the project's characteristics.)

Name and surname(s) of the volunteer: .....
Date and signature of volunteer: .....

Should you have any questions or comments about this project at a later date, or should you wish to withdraw from it, please contact:

Researcher's name: .....
Department, faculty and address: .....
Email and telephone numbers: .....
Date and signature of researcher: .....

Copy for the participant / Copy for the researcher

[1] Instructions: This question should only be included when dealing with special categories of personal data.

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ANNEX 4

SELF-ASSESSMENT OF THE NEED FOR A DATA PROTECTION IMPACT ASSESSMENT

The data protection impact assessment is a procedure intended to identify and control the risks posed to the rights and freedoms of individuals deriving from processing of their personal data. As a general rule, a data protection impact assessment must be carried out when the data processing poses a high risk (Article 35 of the GDPR).

Below is a list of the criteria that may apply to the processing of personal data applicable in the research project. The more of these criteria apply, the more likely the processing is to pose a high risk. In general, a data protection impact assessment will be necessary if the data processing envisaged meets two or more criteria, although it may be advisable even if only one criterion is met.

In order to self-assess the need for a data protection impact assessment, it is necessary to indicate whether the project meets any of the following criteria and to provide the necessary justification.

Project name:		
Criteria		Do the following criteria apply?
	Processing involving profiling or the evaluation of subjects, including the collection of data from the subjects about multiple areas of their lives (performance at work, personality, behaviour), covering various aspects of their personality or about their habits.	Yes / No
	Justification:	
	Processing involving automated decision-making or that largely contributes to such decision-making, including any type of decision preventing a data subject from exercising a right or having access to a good or a service or entering into a contract.	Yes / No
	Justification:	
	Processing involving observation, monitoring, supervision, geolocation or systematic control of the data subject, including the collection of data and metadata through networks, applications or in public access areas, as well as the processing of unique identifiers that enable the identification of users of information society services, such as web services, interactive television, mobile applications, etc.	Yes / No
	Justification:	
	Processing involving the use of special categories of personal data referred to in Article 9.1 of the GDPR, personal data relating to criminal convictions or offences referred to in Article 10 of the GDPR, or personal data that make it possible to determine the financial situation or solvency of individuals or deduce information about them related to special categories of personal data.	Yes / No
	Justification:	
	Processing involving the use of biometric data for the purpose of uniquely identifying a natural person.	Yes / No

	Justification:	
	Processing involving the use of genetic data for any purpose.	Yes / No
	Justification:	
	Processing involving the use of data on a large scale. To determine whether processing can be considered to use data on a large scale, the following criteria are used: • Number of people affected, either as a specific figure or as a proportion of the corresponding population • Volume or variety of data • Duration of processing • Geographical scope of processing	Yes / No
	Justification:	
	Processing involving the matching, combining or linking of datasets from two or more instances of processing for different purposes or by different controllers.	Yes / No
	Justification:	
	Processing of data concerning vulnerable subjects or subjects at risk of social exclusion, including data on minors under the age of 14, adults with some degree of disability, people with disabilities, people accessing social services, and victims of gender violence, as well as their descendents and persons under their guardianship or custody.	Yes / No
	Justification:	
	Processing involving the use of new technologies or an innovative use of existing technologies, including the use of technologies on a new scale, for a new purpose or combined with other technologies, such that they entail new forms of collecting and using data that pose a risk to the rights and freedoms of individuals.	Yes / No
	Justification:	
	Data processing that prevents the data subjects from exercising their rights, using a service or entering into a contract, as well as processing in which the data have been compiled by a controller other than the one who will process them and any of the exceptions concerning the information to be provided to data subjects under Article 14.5 of the GDPR.	Yes / No
	Justification:	
Total number of criteria:		

Date: .....

Name and surname(s): .....