**REPORT REQUEST ON THE ETHICAL ASPECTS AFFECTING RESEARCH WITH HUMAN SUBJECTS**

**MAIN RESEARCHER**

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| --- | --- |
| Name: | Name of main project researcher or name of student responsible for the thesis.  |
| Program: | Name of program currently enrolled in. |
| Email: | Indicate email. |

**PROJECT INFORMATION**

|  |  |
| --- | --- |
| **Title:** | Indicate the complete name of your research. |

**It includes:**

[ ]  of legal age

[ ]  minors

[ ]  students

[ ]  acquired biological samples

[ ]  stored biological samples

**FINDINGS OF THE REC REPORT**

|  |  |  |
| --- | --- | --- |
|  [ ]  Course | [ ]  Master Final Project  | [ ]  Doctoral Thesis |
| Work or Thesis Director: indicate first and last name of the thesis director  |

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| **ATTACHED FILES\*** |
| **1.**  | **This REQUEST with every section filled** |[ ]  Mandatory |
| **2.** | **PROJECT COPY\*\*** |[ ]  Mandatory  |
| **3.**  | **FINANCIAL REPORT** (if the research is financed by an entity) |[ ]  [ ]  Not attached. Justify: If it’s self-financed, indicate it in this section |
| **4.**  | **INFORMATION SHEET AND INFORMED CONSENT(1)(2)(3)(4)(5)** **Download** [**here**](https://drive.google.com/drive/folders/1Vi62HyIwbVXmoeFedFHTs2VA1rKt1inU?usp=sharing) **the available models according to the age of the participants.** |[ ]  [ ]  Not attached. Justify: Justify why an information sheet and informed consent aren’t needed |
| **5.** | **AUTHORIZATION of the relevant authority of the organization/business or school in which the study will be carried out** |[ ]  [ ]  Not attached. Justify: Justify if obtaining said authorization is not possible  |
| **6.** | **DOCUMENTS or SUPPORTING VISUAL MATERIAL or other kind that will be used in the INFORMED CONSENT request** |[ ]  [ ]  Not attached. Justify: Justify here  |
| **7.**  | **DATA COLLECTION INSTRUMENT** |[ ]  [ ]  Not attached. Justify: Justify here |
| **8.** | **APPROVAL DOCUMENT OF OTHER ETHICS COMMITTEE,** in case said Committee exists in the organization in which the study will be carried out. **Submission is MANDATORY if you must fill sections 3, 4 or 5 of this request.** |[ ]  [ ]  Not attached. Justify: Justify here |

\*Requests with incomplete or unjustified information won’t be evaluated.

\*\* The project’s copy, project’s abstract or D1 for master’s programs, or PTD for doctoral programs.

Declaration of commitments:

1. All the information in this document is accurate.
2. I am committed to consider every substantial modification proposed by the Committee for this project.
3. I am committed to inform about any relevant modifications (\*), adverse events or incidents that may occur during the period of study and that may affect the final decision of the Committee.
4. I will not begin any experimental protocol in this project until the Committee has given a complete and definitive supportive report.
5. A record of the experimental process will be kept under my direct supervision, available to any member of the Committee who requests it.

If any of the previous conditions are infringed upon, I understand that the Committee may stop or modify my ongoing project.

**Date :**Click here to write a date.



**Main researcher’s signature**

**(Essential requirement)**

**Signed:** first and last names

(\*) Relevant modification:

* Alteration of projects official
* Alteration of any of the research goals
* Alteration in the use of samples
* Alteration of risks undertaken by the patient
* Alteration of the privacy policy or data protection

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| **1. PROJECT INFORMATION** (6) |
|   **Title:** |  Indicate exact research title  |
| **Abstract:** Write abstract here: Include Main and Specific goals, Justification of the research based on the most updated scientific evidence, planned Methods and Procedures including statical testing and other analytical techniques, bibliography  |

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| **2. GROUPS OF PEOPLE TO BE INCLUDED IN THE STUDY**  |
| Sample process must be explained, and the person or people in charge of the data collection must be indicated. Different groups of participants in the project must be explained. |
| **GROUP** | **DESCRIPTION** | **n\*** | **RECRUITER\*\*** | **RECRUITMENT METHOD** |
| 1 | Click here to write your text. |  |  |  |
| 2 | Click here to write your text. |  |  |  |
| 3 | Click here to write your text. |  |  |  |
| 4 | Click here to write your text. |  |  |  |
| 5 | Click here to write your text. |  |  |  |
| 6 | Click here to write your text. |  |  |  |
| In case of having several groups: Are there enough information sheets and informed consents for each group? (2)(3)(4)(5)[ ]  Yes[ ]  NoJustify Justify here |
| Does this study include any of the following?  | [ ]  Pregnant or breastfeeding women(6)[ ]  Underage participants(7)[ ]  People unable to express their consent, vulnerable population(8)[ ]  Specific ethnic or social groups(8)[ ]  Employees or subordinates as research subjects(9)[ ]  Students or scholarship holders as research subjects(9)Justify and indicate if any additional protection measures have been taken: Justify here |

\*Number of people in said group

\*\*Recruiter’s name

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| **3. RESEARCH THAT IMPLIES PROCEDURES IN HUMAN BEINGS** [ ]  **Not applicable****(Including SAMPLE COLLECTION)** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PROCEDURE** |  |  | **DESCRIBE** | **JUSTIFY** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Will any **UNUSUAL PROCESS** be performed on the patient? Is there any type of **INSURANCE**? (10)(Attach policy or describe insurance company and policy conditions) | [ ] No[ ] No | [ ] Yes[ ] Yes | Describe here.Describe here. | Justify here.Justify here. |
| Is any type of **GENETIC TESTING** going to be carried out?Is there an expert on **genetic counselling** on the team to inform the donor about the results? | [ ] No[ ] No | [ ] Yes[ ] Yes | Describe here.Describe here. | Justify here.Justify here. |
| Will any **QUESTIONNAIRES\*** or **RECORDINGS** be used?\* Attach them | [ ] No | [ ] Yes | Describe here. | Justify here. |
| Are any **NEW BIOLOGICAL SAMPLES** going to be collected? Do they come from **SURPLUS DIAGNOSTIC**  | [ ] No[ ] No | [ ] Yes [ ] Yes | Describe here.Justify here. | Justify here.Justify here. |
| **Why are the samples being collected?** |
| **1.** [ ]  **Use in the RESEARCH PROJECT\*.**  \* Once the INFORMED CONSENT is obtained, the subject must receive an INFORMATION SHEET (IS) of the PROJECT.In case the remaining samples are considered to be preserved in a Biobank, this must appear in the IS (11) and the subject will receive a DIPTYC from the Biobank. If the remaining samples want to be saved in a collection, this must appear in the IS (12). | **Indicate the destination of the samples once the study is over:** |
| [ ]  **Destroyed** |
| [ ]  Addition to a **collection**\*. First Name: Indicate collection’s name.\* Must appear in the project’s IS. |
| [ ]  Incorporation into a **Biobank.** First Name: Indicate collection’s Biobank.\* The subject must receive the Biobank’s IS. |
|  |
| **2.** [ ]  Incorporation into a **collection**\*. First Name: Indicate collection’s name \* Must appear in the project’s IS. |
| **3.** [ ]  Incorporation into a **Biobank**\*Name: Indicate Biobank’s name. \* The subject must receive the Biobank’s IS. |

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| **4. RESEARCH WITH STORED BIOLOGICAL SAMPLES** (13)  [ ]  **Not applicable** |
| Sample origin | [ ]  Biobank’s name: Indicate Biobank’s name[ ]  Registered collection\*. Collection’s name: Indicate collection’s name\*Attach Biobank’s responsibility sheet or the approval of the person in charge of the collection. |
| Type and number of samples | Group 1 | Indicate type and number of samples of Group 1. |
| Group 2 | Indicate type and number of samples of Group 2. |
| Group 3 | Indicate type and number of samples of Group 3. |
| Group 4 | Indicate type and number of samples of Group 4. |
| Group 5 | Indicate type and number of samples of Group 5. |
| Were they obtained prior to the implementation of the Biomedical Research Law 14/2007 (July 5, 2007) (14) | [ ]  Yes | Explain: Explain here |
| [ ]  No |
| Will the samples remain anonymous? Explain here |

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| **5. RESEARCH WITH HUMAN CELLS**(14) [ ] **Not applicable** |
| [ ]  Human cell lines: Specify here [ ]  Fetal cells and tissue of human origin: Justify here[ ]  Oocytes, adult or embryonic stem cells : Justify here |

## 6. RESEARCH THAT IMPLIES INTERVENTION\*

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| **Is any type of intervention going to be carried out?**[ ]  No[ ]  Yes**What type of intervention?**[ ]  Medical or clinical test[ ]  Psycho-pedagogical intervention[ ]  Use of evaluation and/or diagnosis tools (for example: surveys)[ ]  Individual or group therapy[ ]  Product testing[ ]  Other (specify): Specify hereMay damages or side effects happen because of the intervention?[ ]  Yes, informing the patient about them in the information sheet[ ]  NoIndicate the planned safety measures, if any:Indicate here the planned safety measures |

\* Planned and justified action that will be carried out on a social group to reach a goal

## 7. INCORPORATION OF PERSONAL DATA (15)

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| **Is personal data being collected?**[ ]  Yes[ ]  No |
| **How is privacy going to be kept?** [ ]  Coding: The researcher will give a code to every subject, so that they may be identified by associating the code to their personal data.[ ]  Disassociating: The information can’t be associated to an identified or identifiable person (anonymous data)Explain the procedure: Explain the procedure here |
| **Is this personal data going to be used for other uses apart from the research?**[ ]  No[ ]  Yes: [ ]  Specify the purposes in the information sheet and informed consent used in the study[ ]  Specify the purposes in the information sheet and informed consent different from the ones used in the studyIndicate the purposes and how is the personal data going to be protected, if any: Explain here |

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| **Indicate the destination of the data once the study is finished**[ ]  Destroyed in Indicate number of years years.[ ]  Incorporation to a database or file without personal data [ ]  Incorporation to a database or file with personal data In case this happens: Who will be responsible of the file (whose data will appear in the information sheet)?:Indicate the name of the person in chargeIndicate the safety measures taken if the data is saved, especially if it involves highly personal data (highly sensitive data): Indicate here the safety measures |

## INSTRUCTIONS

1.      Act 14/2017 *Article 4.1* “The free autonomy of the people willing to participate in a biomedical research or who may contribute to it by providing their biological samples, shall be respected. This requires their prior **written and expressed consent once the appropriate information has been received.**This information must be provided in a written form, and shall include the nature, importance, implications and possible damages or risks, in accordance with the Law. This information shall be provided to people with disabilities in the proper conditions and formats accessible to them as appropriate to their needs. In cases when participants are unable to write, consent shall be given by any legally admissible method that records the participant’s will”.

2.      The written information sheet and the consent form signature are necessary for those studies that collect personal data or require medical proof. The information sheet shall include the nature, importance, implications and possible damages or risks that the study involves and will be written in concordance with the level of education and comprehension skills of the participants. The Information Sheet and the Informed Consent must be  a single document.

3.      The INFORMATION SHEET must include the following paragraph in relation to Data Protection and the ARCO rights of the participants:

“In accordance with the data protection regulations, we inform you, and you expressly authorize, your data to be included within files owned by (indicate institution or company), duly registered in the General Data Protection Register, for the management and operational purposes of the Study”.

By participating in this study, you authorize the use of your clinical data for the purposes of reaching conclusions about the corresponding treatment. Healthcare authorities and members of the Ethics committee will also have access to this data when considered necessary.

Any personal data, including clinical data too, will be treated in accordance with the current laws in force on the protection of personal data (LO 15/1999 on the Development Regulations of the Organic Act of personal data protection) (*Protección de Datos de Carácter Personal y su Reglamento de Desarrollo*).

Your identity will not be revealed by any possible communications stemming from this study.

You can access, rectify, oppose and/or cancel your personal data in our database at any time. To do so, you must contact (indicate an institution or company), as the owner of the file, and we shall send a signed request to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. ”

4.      Research projects requiring personal data must be in accordance with the Data Protection legislation in force of the participant’s country of origin. The Regulations in force in Spain can be found on the Spanish Data Protection Agency’s website (<http://www.agpd.es/>).

5.      Human research projects shall respect all principles set out in the Helsinki Declaration, in the Council of European Convention on Human Rights and Biomedicine, and in UNESCO's Universal Declaration on the Human Genome and Human Rights. They shall be in accordance with the Spanish biomedical research and personal data protection legislation: Organic Law 15/1999 on Personal Data Protection, Law 41/2002 on basic regulation of patient rights, autonomy and obligations on clinical data and documentation, Law 14/2007 on biomedical research, and RD 1716/2011 which regulates Biobanks and research sample use.

6.      Considerations should be given to provisions of Law 14/2007, *Article 19*. “Research during pregnancy and lactation”.

7.      Considerations should be given to provisions of Law 14/2007, *Article 20*. “Protection of persons unable to express their consent”. In cases of minors, permission must be granted by the parents or legal guardians. It is recommended that the parent or legal guardian accompany the child if they are under the age of 14.

8.      Considerations should be given to provisions of Law 14/2007, *Article 20*. “Protection of persons unable to express their consent” and *Article 21.* “Research on people unable to express their informed consent due to their clinical state”.

9.      Special care must be taken throughout the data collection process.

10.   Considerations should be given to provisions of Law 14/2007. *Article 18.* “Compensation for damages and insurance”.

11.   Considerations should be given to provisions of Law 14/2007. *Article 49*. “Right for the need to be and not to be informed”. *Article 55.* “Genetic counseling”.

12.   Paragraph to be added to the INFORMATION SHEET as additional consent for surplus donation to the Biobank:

*“Once the project is completed, surplus shall be destroyed. However, we ask your permission to donate it to the following Biobank: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Samples and their derivatives marked with a donor code will be incorporated to the Biobank and will be stored until exhausted in conditions of order, security and prevention of incidences”.*

The CONSENT FORM must include the following:

*I hereby allow my sample to be included in the Biobank........................... .................................................................................   YES* ˆ*NO*ˆ

13.   Paragraph to be added to the INFORMATION SHEET as additional consent for surplus donation for purposes of collection:

*“As an additional request, we ask for your surplus samples, if any, to be incorporated to the "XXXXXXXXXXX” collection, registered in the National Registry of Biobanks with the number XXXXXXXX, which will be safeguarded by Dr. XXXXXX from the (indicate a institution).  If you agree to this, your samples may only be used in the future for scientifically endorsed research projects approved by a Research Ethics Committee. The researcher in charge of your surplus will have at their disposal all the information concerning the projects in which your sample will be used. If you do not agree to this, your surplus samples shall be destroyed once the analysis phase of the project is completed”.*

The CONSENT FORM must include the following:

*I hereby allow my sample to be incorporated to the following Collection: ........................... .................................................................................  YES* ˆ*NO*ˆ

14.   Considerations should be given to provisions of Law 14/2007. *Article 61*. Storing and destruction of samples”.

15.   Considerations should be given to provisions of Law 14/2007. *Article 34*. Research warranties and requirements”. *Article 35*. “Report of the Commission on Guarantees for the Donation and Use of Human Tissues and Cells”.

16.   Considerations should be given to provisions of Law 14/2007. *Article 5*. “Protection of personal data and guarantees of confidentiality”.

17.   Considerations should be given to provisions of Law 14/2007. *“Coded or reversibly disassociated data”*: means data not associated with an identified or identifiable person because the information that identifies said person has been replaced or unlinked using a code that allows reverse operation.