**Request for a report on ethical aspects that affect research with human beings**

## MAIN RESEARCHER([[1]](#endnote-1))

|  |  |
| --- | --- |
| Name: |       |
| Center/Faculty([[2]](#endnote-2)): |       | Unit/Departament: |       |
| Telephone: |       | Email: |       |

## DOCUMENTS ATTACHED\*

|  |  |  |  |
| --- | --- | --- | --- |
| **1.**  | **This APPLICATION with all the sections completed**  | [ ]  | Required |
| **2.** | **PROJECT COPY** **(Indicate the VERSION number)**  | [ ]  | Required  |
| **3.**  | **ECONOMIC REPORT**  | [ ]  | [ ]  N/A. Justify:       |
| **4.**  | **INFORMATION SHEET for the subject and INFORMED CONSENT** **for each applied technique and participating group(**[[3]](#endnote-3)), (6)  | [ ]  | [ ]  N/A. Justify:       |
| **5** | **Questionnaires, advertisements, etc.** **that will be used in the project**  | [ ]  | [ ]  N/A. Justify:       |
| **6.**  | **In the case of using an already available database:** Authorization for its use signed by a person in charge and/or its privacy policy  | [ ]  | [ ]  N/A. Justify:       |
| **7.**  | **In the case of carrying out the study in an institution (study center, hospital,** **etc.):** Document showing the presentation of the study to request the center’s participation. | [ ]  | [ ]  N/A. Justify:       |
| **8.**  | **Others** (specify):       | [ ]  |  |

\* Please, remember that those applications presenting incomplete or unsupported documentation will not be evaluated.

**PROJECT DATA**

|  |  |
| --- | --- |
| Title: |       |
| Start date: |       |  |  |

[ ]  Approved by another CEI. If yes, attach certificates.

Is there a conflict of interest? [ ]  No [ ]  Yes (declare):

**PURPOSE OF THE CEI REPORT**

|  |
| --- |
| [ ]  Modification of approved project (indicate code)      [ ]  Final Degree Project (TFG) [ ]  Master's Thesis (TFM) [ ]  PhD ThesisDirector of project or thesis (name and surname[s]): Work Center: [ ]  Presentation of project to be financed: Agency:       Announcement :       |
| [ ]  Financed project in execution                 Agency:       |
| [ ]  Authorization of activity or experimentation without financing body |
| [ ]  Others (publication, etc.). Specify |       |

Declaration of commitments:

a)   All information contained in this document is true.

b)   I undertake to take into consideration all the substantial modifications proposed for this project by the Committee.

c) I undertake to report any relevant modification(\*), adverse event or incident that may occur during the study period and that affects the final decision of the Committee.

d) I will not begin any experimental protocol contained in this project until its complete and definitive favorable report by the Committee.

e) Records of the experimental process will be kept, under my direct supervision, available to the members of the Committee that so request.

If any of the above conditions are not met, I understand that the Committee may stop or modify the ongoing project.

**Date :**       **Signature Main Researcher**

 **(essential requirement)**

 **Signed:** Name and surname(s)

(\*) Relevant modification:

-           change in project manager

-           change in any of the project objectives

-           change in risk to which the patient is subjected

-           change in privacy or data protection policy

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| SECTIONS OF THIS APPLICATION |
| **1. PROJECT DATA** **2. ORIGIN** **AND CHARACTERISTICS** **OF INFORMATION** **3. GROUPS OF PEOPLE TO BE INCLUDED IN THE STUDY** **4. RESEARCH THAT INVOLVES INTERVENTION** **5. INCLUSION OF PERSONAL DATA** **Explanatory notes**  |

## 1. PROJECT DATA

|  |  |
| --- | --- |
|  Title: |       |
| Abstract:       |

## 2. ORIGIN AND CHARACTERISTICS OF THE INFORMATION

|  |
| --- |
| **Indicate the origin of the information to be used:**[ ]  Database or external information source[ ]  For public access and privacy policy that allows its use in research [ ]  Private but with permission for its use provided by the person in charge and/or by its privacy policy[ ]  Information collected in this research(3)[ ]  Anonymous information[ ]  Information with personal data([[4]](#endnote-4)), ([[5]](#endnote-5)) for whose collection an information and informed consent sheet has been developed([[6]](#endnote-6))[ ]  Special categories information([[7]](#endnote-7)) for whose collection an information and informed consent sheet has been developed(6)How do you obtain the information?([[8]](#endnote-8))[ ]  Through standardized instruments([[9]](#endnote-9))[ ]  Through non-standardized instruments([[10]](#endnote-10))[ ]  Through images, audio or videos([[11]](#endnote-11))[ ]  Other (please, specify):  |

## 3. GROUPS OF PEOPLE TO BE INCLUDED IN THE STUDY

|  |
| --- |
| **Describe the groups of participants and indicate who recruits them** **(name, position and workplace)** **and how**([[12]](#endnote-12)) |
| **GROUP**  | **DESCRIPTION**  | **n**  | **RECRUITER**  | **RECRUITMENT METHOD**  |
| 1 |       |  |       |       |
| 2 |       |  |       |       |
| 3 |       |  |       |       |
| 4 |       |  |       |       |
| 5 |       |  |       |       |
| **In the event that there are several groups: Are Information and Informed Consent Sheets planned for each group?(6)**[ ]  Yes[ ]  NoJustify:  |
| **Does the study include...?**[ ]  Minors([[13]](#endnote-13))[ ]  Persons unable to express their consent([[14]](#endnote-14))[ ]  Specific ethnic or social groups([[15]](#endnote-15))[ ]  Employees or subordinates\* [ ]  Students or grantees\*Justify and indicate whether additional protection measures are planned: \* If they belong only to the University of Navarra, as established by the University, the project must have the approval of the Board of Directors of the Faculty to which the study belongs. Yes, I have the aforementioned approval (mark with an X) [ ]   |

## 4. RESEARCH INVOLVING INTERVENTION

|  |
| --- |
| **Is some kind of intervention going to be performed**([[16]](#endnote-16))**?**[ ]  No[ ]  Yes**What kind of intervention?**[ ]  Medical or clinical test([[17]](#endnote-17)), (6)[ ]  Psychopedagogical intervention([[18]](#endnote-18))[ ]  Application of evaluation and/or diagnostic instruments([[19]](#endnote-19))[ ]  Individual or group therapy[ ]  Product test([[20]](#endnote-20))[ ]  Other (specify): ………………………………………………Can damage or side effects occur due to the intervention?[ ]  Yes, informing the participant thereof on the Information Sheet(6)[ ]  NoIndicate protective measures envisaged: |

## 5. INCLUSION OF PERSONAL DATA

|  |
| --- |
| **Is personal data collected?**(4) [ ]  Yes(6)[ ]  No |
| **How will confidentiality be preserved?** [ ]  Coding or pseudoanonymization: The researcher gives a code to each subject which identifies them only by associating the code to personal data (this information being duly safeguarded)[ ]  Dissociation: The information cannot be associated with an identified or identifiable person (anonymous data)Explain the procedure:       |
| **Is the database expected to** **be** **transferred outside the European Union?**[ ]  No[ ]  Yes, anonymous data[ ]  Yes, personal data will be transferred but the receiver guarantees the same level of data protection security as in the European Union  |
| **Will personal data be used for purposes other than research?**[ ]  No[ ]  Yes(6), (11) Indicate:[ ]  The uses are specified in the information and informed consent sheet used in the study[ ]  The uses are specified in an information and informed consent sheet other than those used in the study Indicate the purposes and how the personal data will be protected, if any:  |
| **Indicate the destination of the data at the end of the study**(6)[ ]  Destruction within ……….years (indicate period) [ ]  Incorporation into a database or file without personal data[ ]  Incorporation into a database or file that includes personal data(11)In the latter case: Who will be responsible for the file (whose data will appear on the information sheet)?: Indicate the security measures to be taken in the case of saving the data, especially if they include high-level personal data (of special categories)(7):  |

**Explanatory notes**

1. Data of the main researcher of the project or of the PhD student responsible for the thesis. [↑](#endnote-ref-1)
2. Indicate Center/Faculty and Department of the University of Navarra. [↑](#endnote-ref-2)
3. Participants in a study must grant their express consent once the appropriate information has been received. If it is an anonymous questionnaire, consent is understood as having been granted by agreeing to answer it. On the other hand, if the study is carried out in the environment of an institution such as a teaching center or hospital, for example, you must have written permission from the person responsible for it. [↑](#endnote-ref-3)
4. According to Article 4 of Regulation (EU) 2016/679 on the Protection of Natural Persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), data of a personal nature is “any information relating to an identified or identifiable natural person (the 'data subject'); 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, 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”.

When collecting data to identify a person (surname, image, voice or video recording...), it will be necessary to include the following text on the data protection of the participants on the INFORMATION SHEET:

*All personal data, including clinical data, will be processed in accordance with current data protection laws, especially pursuant to the Regulation (EU) 2016/679 of the European Parliament and of the Council, of April 27, 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (hereinafter GDPR) and Law 3/2018 of December 5 on Data Protection and Guarantee of Digital Rights (LOPD).*

*The Data Processing Officer (UN), in compliance with GDPR, informs you that if you participate in this study, your clinical data will be processed by the research team in order to draw conclusions from the Project. The health authorities and the members of the ethical committee may also access the data if they deem it necessary*

*It will not be possible to identify you through the communications that this study may generate.*

*You are responsible for the accuracy and correctness of the data you give us and you have the right to exercise the rights of access, rectification, deletion, limitation of the processing, portability and opposition of your data in accordance with the provisions governing data protection. To exercise the above, you must write to the UN Data Protection Delegate at the following postal address:* Campus *Universitario, s/n, Edificio Central. 31080 Pamplona (Navarra, Spain), or to the email address* *dpo@unav.es**. In any case, you must attach a photocopy of your national identity document or equivalent.*

*If you do not agree with the processing carried out by our Institution or consider your rights violated, you have the right to file a complaint with the Spanish Data Protection Agency.*

For more information, click this link: [*More*](https://www.unav.edu/documents/11314/6015690/Texto%2B2%C2%AA%2Bcapa%2Bclausula%2Bprivacidad%2Binvestigacion%2Bsanitaria_abril2019.pdf) *on data protection* [↑](#endnote-ref-4)
5. Research projects that involve the use of personal data must respect the Data Protection legislation in force in the country of origin of the participating subjects. You can consult the regulations in force in Spain on the website of the Spanish Agency for Data Protection ([www.aepd.es/](http://www.aepd.es/)). [↑](#endnote-ref-5)
6. The written **information sheet** and the signature of the **informed consent** **form** are necessary in the case of studies involving the collection of personal data or when medical evidence is required. The information will include the nature, importance, implications and possible damages or risks derived from the research (if any) and the destination of the information. They will be written according to the training and understanding of the persons involved. You can consult this committee’s document on the minimum contents of this document and recommendations in special cases. [↑](#endnote-ref-6)
7. Specially protected data (special category data) requires greater protection and is that revealing ethnic or racial origin, genetic data, biometric data aimed at uniquely identifying a natural person, health-related data or the sexual life or sexual orientations of a natural person. [↑](#endnote-ref-7)
8. The methods applied should not harm the participants and the time required for active participation should be minimized. [↑](#endnote-ref-8)
9. Standardized instruments are those tests, inventories, questionnaires, etc. widely used for the desired measurement or that are supported by previous research. [↑](#endnote-ref-9)
10. In the event that your own (not standardized) instruments are used as a questionnaire expressly developed for the study, proper training is recommended for its preparation in addition to the conducting of a pilot test to allow for assessment of its quality. [↑](#endnote-ref-10)
11. In these cases, it is important to inform the subject and obtain his or her explicit consent on this aspect. [↑](#endnote-ref-11)
12. Explain the sampling process, if any, and indicate the person responsible for data collection. If there is a control and experimental group, indicate this when explaining the groups. [↑](#endnote-ref-12)
13. In the event of interaction with minors, it is necessary to obtain the permission of parents or guardians. It is recommended that the person in charge remain with the child if he or she is under 14 years old. [↑](#endnote-ref-13)
14. In the case of persons with disabilities, one should act as if they were minors. If the subject of the research cannot write, consent may be given by any method allowed by law that enables recording of the person’s intent. [↑](#endnote-ref-14)
15. In the case of groups vulnerable due to their ethnic or social situation, it will be necessary to take special care of the entire data collection process. [↑](#endnote-ref-15)
16. "Intervention" refers to the application of special teaching methods, therapies or tests, such as those indicated in the table. [↑](#endnote-ref-16)
17. Research projects involving medical studies on human beings must respect the principles established in the Declaration of Helsinki, in the Council of Europe Convention on human rights and biomedicine and in the UNESCO Declaration on the Human Genome and Human Rights. They must comply with Spanish legislation in the field of biomedical research, Basic Law 41/2002 regulating patient autonomy and rights and obligations of information and clinical documentation, Law 14/2007 on biomedical research, in addition to the General Protection Regulation of Data. [↑](#endnote-ref-17)
18. Different teaching method, treatment of a learning disability, re-education of a language disorder, etc. [↑](#endnote-ref-18)
19. Intellectual quotient measurement test, for example. [↑](#endnote-ref-19)
20. Tests of a food product, for example, should be carried out in appropriate environments taking care of aspects such as storage and handling. In the case of products such as alcohol or tobacco, compliance with their respective laws is necessary. [↑](#endnote-ref-20)