 **CER SUBMISSION FORM**

The CER (Research Ethics Committee) examines research protocols carried out under the responsibility of a researcher

or a tenured teacher-researcher associated with the institutional community

of Université Fédérale Toulouse Midi-Pyrénées

**Questions concerning the submission:**

If this is the 2nd or 3rd submission, please include the file reference number: **\_\_\_\_\_\_\_\_\_\_\_**

I solemnly declare that the collection of data for this research has not been initiated.

I am aware of the fact that the decision issued by the CER **will be sent to the Head of the Research Unit within which I carry out my research activities.** I have included the **Last Name-First name and email address** of the Head of the Research Unit: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I would like to obtain **simple ethical advice** from the CER. The scientific project will only be assessed if the committee is required to consider a cost/benefit ratio in its assessment of the ethical questions raised by the project.

I would like to obtain **an IRB number valid for one year**. In this case, I understand that my project will be systematically evaluated from **an ethical as well as a scientific point of view**. I have also taken note that the CER expects **a justification for an IRB application**, more than requesting a simple ethics assessment (e.g., expected publications in journals requiring an IRB registration and not only an ethics committee’s approval, international collaboration requiring each partner to obtain an IRB approval, international funders requiring an IRB approval, etc.).

**Justification of the IRB registration request**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I am aware of the fact that **the decision issued by the CER only concerns the research project presented in this document.**

In the case of data collection via the internet, I solemnly undertake to check that the platform does not record the IP addresses of the participants, and if necessary to set up the platform in such a way that it does not record the IP addresses of the participants.

I am aware of the instructions concerning **compliance with the data protection regulations in force.** Reference texts:

* Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text of interest for the EEA)
* French Data Protection Act (Law 78-17 of 6 January 1978, amended) concerning information technology, data files and civil liberties.

If your research involves the handling of personal data (studies, surveys, interviews, video and voice recordings, etc.), it is subject to compliance with the fundamental regulatory data protection principles.

All the people involved in the research will be unfailingly vigilant regarding compliance with the regulation and able to prove conformity prior to implementation of data processing by keeping an up-to-date record of detailed documents (GDPR compliance file, compliance with a baseline CNIL methodology, impact analysis of data processing on privacy, notification of data breaches, contractual record of conformity between people involved / data transfers outside of the EU).

To ensure you are aware of the obligations related to your research, and take the necessary steps to make your data processing operations compliant, the CER encourages you to contact the competent Data Protection Officer (DPO) for the research unit responsible for the study (find out more about the GDPR <https://www.cnil.fr/>)

The CER does not deal with the subject of intervention research on *people*. For this type of research, please contact the committee for the protection of persons.

**Caution regarding research partially carried out outside of France** The CER does not issue a verdict concerning the part of a research protocol carried out outside of France, which must be submitted to a local ethics committee or a committee familiar with local customs [except if a researcher belonging to a member institution of Université Fédérale de Toulouse carries out his/her research in a country which does not have a research ethics committee].

**Date: Electronic signature of the scientific coordinator:**

1. **Project title:**
2. **PROJECT SUMMARY (max. 1 page)**
3. **Scientific field:**
4. **Tenured researcher (only 1), scientific coordinator for the project (must be a researcher or statutory teacher-researcher):**

*Please ensure you provide us with all the following information: last name and first name, email and phone no., position, affiliation and postal address*

1. **Other researchers taking part in the project:**
2. **Place(s) of research (place or places where the study will be conducted):**
3. **Main objective (max. 5 lines):**

* **BRIEF DESCRIPTION OF THE PROJECT**

**Context and scientific interest:**

*Healthcare application, industrial application, furthering scientific knowledge, for the benefit of society, etc.*

***Your project is likely to be read by the non-scientific members of the CER, or by members of a scientific discipline other than your own. Please therefore avoid or explain any specialist scientific terms and all acronyms.***

**Objectives:**

**General assumptions:**

***Conflicts of interest:***

*To the best of your knowledge, do any of the researchers involved in the project have a vested interest (either personal or institutional) or conflict of interest with regard to a partner, financial backer or any other institution? If so, please describe the situation in question, the identity of the people involved and, if possible, how the investigators plan to neutralise the interactions. A conflict of interest does not necessarily imply that a negative decision will be delivered, but the CER considers it extremely important that any vested interest or conflict of interest be declared by the researchers.*

* **MATERIALS AND METHODS**
* **Participants**

**Exact number of participants or approximate “range” and criteria used to determine this number:**

The CER expects the project owner to justify the number of participants to be enlisted, based on the existing literature and use of a software application that estimates the number of participants required based on the estimated effect sizes (the open-source software programme G\*Power, for example, is able to perform this calculation).

**Recruitment:**

Recruitment mode: *adverts, listings, “word of mouth” effect, etc.*

Place of recruitment: *specify the planned place of recruitment or the criteria that will determine the choice of place*

Selection criteria: *specify the selection criteria for participants, based on your research objectives. These criteria may include aspects such as age range, manual laterality, socio-cultural background, level of education, nationality, involvement in the process studied, etc.*

Non-inclusion criteria: *specify the non-inclusion criteria applied to potential participants, based on your research objectives. These criteria will come into play once you have selected your participants, i.e. they will lead to some of the pre-selected participants being excluded from your protocol. These criteria may include aspects such as visual or hearing impairments, neurological disorders, addictive behaviour, etc.*

Recommendations: *in order to minimise the risk of any invasion of privacy, we recommend that you list all the criteria (inclusion and/or exclusion) and ask participants whether they meet all the criteria, rather than asking them whether they meet each criterion one by one.*

**Possible compensation for subjects:**

*Do you plan to offer compensation to the people involved in the research? If so, you need to specify this and describe the chosen form.*

* **Method**

**Description of the protocol:** *tasks, questionnaires, etc.*

**Materials used:** *it is important that we are clearly informed about the materials you plan to use (e.g. questionnaires, interview framework, etc.) so that we are able to judge whether they pose a risk to your participants. In the specific case of the EEG, include a prior test of the gel on the hand, to make sure that the person is not allergic. Specify the technical characteristics of the technical materials used (sound recording, video, focal distances used, etc.)*

**Place where the study will be carried out:**

**Timetable of assessments or observations:** *start and end dates (month and year), number of assessment sessions for each participant, duration of the assessment for each participant. This information may be presented in the form of a table.*

**Duration of the study:** *this corresponds to the amount of time required to collect the data*

**Data analysis:** *Description of the data analysis (quantitative and qualitative)*

* **Foreseeable or known benefits and risks to physical and mental health (self-esteem, etc.) and social life (reputation)**
* *Present the benefits of your study. These benefits may include scientific progress, improving quality of life for participants, boosting self-esteem, etc.*
* *You must answer yes or no in the table below in order to list the risks that you may encounter during your study. For each one, you need to specify the risk prevention means.*

*Under the table, describe any other risks related to your study. For the latter, and for the risks included in the table, you must specify, for each one, the risk prevention means or the procedures to be implemented if the risk materialises (e.g. if a subject starts to panic). If a risk is present, you will explain how you plan to handle it, ensuring you take every possible precaution to protect your research participants.* *The notion of risk covers all aspects of the person (physical, psychological, relational, emotional, social, etc.). For example, a simple inconvenience may constitute a risk and must be mentioned. Special care must be taken when vulnerable categories of people are involved: prisoners, children, pregnant women, etc.*

Answer **yes or no** in the relevant field:

|  |  |
| --- | --- |
| Yes/no | List of risks: **For each identified risk, please provide the reason why you need to take this risk and indicate all the precautions you will undertake to limit this risk as much as possible and to deal with the occurrence of any related problem (insert your text in the corresponding box and highlight it in green)** |
|  | Does your protocol use a form of staging designed to conceal part of the objective or methodology from the subjects, or to make them believe that other objectives or methodologies are at stake?*If so, this submission needs to provide a description of the type of staging used and an explanation of the way it will be revealed to the subjects at the end of the study, and how they will be informed of the study’s true objectives. In addition, you need to provide arguments showing that it is absolutely necessary, given the objectives and issues at stake, to conceal certain aspects of the protocol, and that none of the aspects concealed from the subjects poses a threat to their safety or dignity.* |
|  | Questions or situations that may cause participants to feel uneasy? |
|  | Materials likely to be perceived by the participants as threatening, shocking or repulsive? |
|  | Possible invasion of participants’ privacy, or that of their family, including the use of personal information? |
|  | Use of physical stimuli (sound, visual, haptic, etc.) other than stimuli associated with everyday activities? |
|  | Deprivation of physiological needs (drinking, eating, sleeping, etc.) |
|  | Handling of psychological or social parameters such as sensory deprivation, social isolation or psychological stress? |
|  | Physical exertion more demanding than a level that would be considered moderate for the participant? |
|  | Exposure to drugs, chemical substances or potentially toxic agents? |

* **Vigilance/ Early termination of the study**

**Criteria leading to termination of the study for one of its participants:**

*Example: A subject withdraws his or her consent to take part in the study during or after the data collection phase.*

* **DATA PROCESSING - RESPECT FOR THE PARTICIPANT’S PRIVACY**

*The project owner must specify the conditions in which the information collected will be processed, anonymised and stored, and the measures taken to guarantee respect for privacy with regard to the implementation of the protocol and publication of the results of the study. He or she must provide all the questionnaires used in the study, as the case may be, and their references (if a standardised tool was used), and explain the way they were conducted (paper format, online, interview, etc.).*

* **Confidentiality**

**Anonymisation process:**

*The notion of data anonymisation goes beyond simply hiding the person’s name. It means that it should be impossible to match the subject’s identity with the data, even using indirect means. Generally speaking, confidentiality will be guaranteed by the fact that each subject or group will be referred to by an identification code in the form of a random number in electronic and paper analyses and documents.*

*However, there are two different cases when it comes to protecting privacy and confidentiality.*

*Case 1 - The protocol is such that the data processed is anonymous or made anonymous via the use of random numbers. The person involved cannot be identified in any way, even indirectly; consequently, this data can no longer be considered to be personal data, and there is no table of correspondence between the identity of each person and a random number referring to a set of individual data.*

*Case 2 - The data is classified as personal data or there is a table of correspondence between each person and the random numbers identifying the set of data related to a given participant (this scenario may be justified by the research objectives).*

*In this second case, we talk about confidentiality rather than anonymity (people are identified or identifiable in the documents, even partially or temporarily). The principle of confidentiality rather than anonymity will hence be invoked. In such cases, please specify:*

* *the reason why anonymisation is not possible*
* *a description of possible breaches of people’s right to privacy resulting from the project or publication of the results,*
* *the precautions taken to handle this risk.*

**People authorised to access this data:**

*Please specify the people who will have access to the data: scientific coordinator, research associate(s), etc.*

* **Archiving**

**Type of data archived (specify whether the data can lead to identification of the subjects, either directly or by cross-referencing):**

**Duration of archiving:**

The CER advises an archiving period of 15 years after data collection. In any case, a duration of 5 years after publication is the absolute minimum. With regard to archiving of the consent forms (which inevitably enable identification of the subjects), the CER recommends that they be retained for 10 years from the publication date and 20 years if the results are not published, in a sealed envelope marked: “I certify that this envelope contains x (number) consent form(s) and x compliant information form(s), collected as part of the study xxx”, followed by the name of the person responsible.

**Place of archiving:** With regard to digital archiving, the CER advises using only professional, encrypted, password-protected computers and secured remote servers. If you wish to use the digital environment of a university, please check with the IT department if it has an appropriate level of security. Always encrypt your research folders. Note that Huma-Num server has an appropriate level of security for long-term archiving.

**Person responsible:** (principal investigator)

**Data may be destroyed at the request of the participant *(ref. specific case outlined in section 4)*:**

* **INFORMED CONSENT FORM INCLUDING THE INFORMATION TO BE GIVEN TO PARTICIPANTS**

*The file submitted to the CER must include a consent form containing the information given to the participants, to be signed by the subjects, and any posters used to recruit them. In cases where pre-assessment involving a series of tests is used as an inclusion criterion for selecting the subjects, the consent form must be signed before these tests are taken.*

***Specific points concerning the information given to participants:***

All pre-selected participants will be informed beforehand by the scientific coordinator of the objectives of the study, its methodology, duration and the *foreseeable constraints and risks, except in cases where the initial assessment test must be taken without the person being aware of the objective. In such cases, please provide scientific justification for the decision not to provide any information beforehand and explain how participants will be made aware of this information later on (debriefing), as well as how they will be informed of their right to withdraw from the study once all the information about the objectives has been provided. A summary of the information given by the scientific coordinator will be provided in the consent form (Appendix no.1).*

*Generally speaking, the information given to participants in order to elicit their consent must be clear, legible and concise (avoid or explain any specialist scientific terms). The document must be written in a language which the subject understands (French by default, or another language if required; consult the CER to determine whether a translation needs to be provided). Remember to adapt the content of the form below to your research protocol and the target audience (e.g. information intended for children needs to be adapted in terms of form and content).*

*The consent form must be based on the template below (Appendix 1). It must state the right to refuse, the possibility of withdrawing from the study at any time and the right to monitor the results, and include contact details for the scientific coordinator. Participants will be clearly informed that they are entirely free to refuse to participate in the study or to withdraw their consent, without incurring any loss as a result. For example, if the participants are students, you must clearly state that any refusal or withdrawal will have no impact whatsoever on their exam results or the teacher-student relationship. If the participants are patients, you must clearly state that their participation in the study - or their refusal to participate in or withdrawal from the study - has no impact whatsoever on the treatment provided. They will be informed of their right to rectify or destroy their personal data. However, with regard to this right, it is important to make a distinction between the two cases described in part A of section 3:*

*Case 1 - Inform the participants that the strictly anonymous nature of the study makes it impossible to rectify or erase their personal data once they have participated.*

*Case 2 - Inform the participants that, in accordance with the provisions of the French Data Protection Act, they may exercise their right to access, rectify or erase their personal data by contacting the project’s scientific coordinator.*

***Specific points concerning signature and provision of the informed consent form to the participant:***

*After making sure that the person concerned has properly understood the information provided, the scientific coordinator will elicit his or her consent to take part in the study. If they accept, they will sign two copies of the consent form prior to the start of the study (Appendix no.1). The scientific coordinator will keep one of the copies and hand the other one over to the participant.*

**Please describe how informed consent will be obtained:**

*For specific cases, such as children, people in a vulnerable position and people under guardianship, please contact the CER office.*

In order to increase your chances of obtaining a positive decision from the CER, please confirm that all the following precautions have been taken by ticking “yes”:

|  |  |
| --- | --- |
| **Yes** | **Precautions** |
|  | **Data storage and security.** Data storage involves the use of secure applications (e.g. secure cloud, server with a high security level, use of email addresses and communication means provided by the research institution, no recording of IP addresses, archiving by a lead researcher in a secure location such as a locked cupboard, archiving duration consistent with the data anonymity period). |
|  | **Data anonymisation procedure.** Data anonymisation must be performed (e.g. use of random numbers for each participant). Failing that, confidentiality will be guaranteed. In this case, there is a table of correspondence between the identity and the number, which must be retained by a lead researcher in a secure location. We recommend that you use the applications provided by the research institution for data collection, e.g. Limesurvey or Qualtrics, rather than social media. The platform must be configured in such a way that the IP addresses of the participants are not recorded. |
|  | **Full set of materials.** The questionnaires, interviews, appendices, trial task and/or instructions given to participants must all be provided. If an item is in the process of being developed (e.g. questionnaire) or likely to change (e.g. interview), information about the item concerned must be provided (e.g. interview framework). |
|  | **No excessive data collection.** In accordance with the General Data Protection Regulation (GDPR), no excessive or unnecessary data will be collected. All the information collected must have been clearly thought out (e.g. no need to know the exact date of birth, just the year, do not record socio-professional category if there are no underlying assumptions related to this information, no need to specify the various psychological disorders in the list of exclusion criteria - suffice to mention the presence of a psychological disorder in general terms). |
|  | **Legibility of the explanations and consent form.** These documents must be adapted to the comprehension skills of the people involved in the study. It is better to avoid highly technical terms. |
|  | **Declaration to the Data Protection Officer (DPO).** When you submit your file to the CER, you also need to contact a DPO. |
|  | **No potential conflict of interest when administering the tests**. For data collection, we advise you to enlist the services of a person (e.g. doctoral student) who does not have any conflict of interest with regard to the participant, and to avoid administering the tests in conditions that may involve a conflict of interest (e.g. by the person's general practitioner). Participants must not be put under any pressure. |
|  | **If the study is likely to induce a feeling of discomfort, specify the procedure to be implemented to deal with the situation**. E.g. provide contact details for a psychologist if psychological discomfort is a possibility. |

**APPENDIX 1 - INFORMATION SHEET AND INFORMED CONSENT**

***Reminder: The information given to participants in order to elicit their consent must be clear, legible and concise (avoid or explain any specialist scientific terms) and adapted to the people for whom it is intended.***

For example, if the participants are children, make sure you explain how the study will be carried out, the fact that they are entitled to withdraw from the study at any time, etc., using very simple vocabulary so that the children are able to understand. We underline the importance of adapting the language you use to provide information to participants (adults, older people, children, parents of children, patients, guardians) who are not scientists or members of an ethics committee.

**Project title:**

**Tenured researcher, scientific coordinator of the project:**

*Please provide all the following information: last name and first name, email address and phone number, position, affiliation and postal address.*

**Place of research:**

**Goal of the research project:**

**What we expect of you (methodology):**

*Please use this section to provide the participants with an explanation of what they will have to do and the experimental conditions in which they will be observed.*

*Example - If you agree to participate in this study, you will take part in an experiment during which you will associate words and images. We will then record your eye movements while you listen to sentences containing these same words and select the corresponding image (the experiment will last for around 25 minutes). At the end of the experiment, you will fill in a questionnaire that will ask you to give information about your knowledge of languages and your learning of French (this part will last for around 5 minutes).*

**Your right to withdraw from the research programme at any time:**

*Make sure the participants are fully aware of the following points: 1/ their contribution to the research is voluntary; 2/ they are entitled to withdraw or stop participating at any time; 3/ their decision to participate, to refuse to participate or to stop participating will have no impact whatsoever on their marks, status or future relations with laboratory X or University Y.*

**Your right to confidentiality and respect for privacy:**

*Make sure the participants are fully aware of the following points: 1/ the data obtained will be processed with the utmost confidentiality; 2/ their identity will be concealed via a random number; 3/ no other information that might reveal their identity will be disclosed; 4/ all data will be kept in a secure location and only the scientific coordinator and the associate researchers will have access to it; 5/ with regard to the right to destroy or rectify data later on, include information depending on whether case 1 or case 2 applies (as described in sections 3 and 4).*

**Benefits:**

*Example - The expected advantages of this research are to improve our understanding of the factors that influence the way native and non-native French speakers perceive French words. Improving our understanding of these factors may help improve the teaching methods used by teachers of French language classes.*

**Possible risks:**

*Except for risks related to the staging method used to conceal the true objectives of the study, which will be explained to the subjects later on (refer to section 2c), please use this section to list the risks you described in the protocol and the risk prevention means or procedures to be implemented if the risk materialises.*

*Example - To the best of our knowledge, this research does not involve any risk or discomfort other than those involved in everyday life. Eye movements are recorded using a device that reflects infrared light from the pupil and cornea of the eye. The pupil and cornea absorb a small amount of energy from the infrared light, but this energy is below the authorised threshold stipulated by international recommendations (American Standards Institute: ANSI Z 136.1-1973). It is about the same amount of light you would absorb in the course of a sunny day.*

**Publication:**

*Example - This research will be shared during conferences and published in conference reports and articles in academic journals.*

**Your right to ask questions at any time:**

*Example - You can ask questions about the research at any time by contacting the project’s scientific coordinator via email at X (or by phone at Y).*

**Consent prior to participation:**

By signing the consent form, you certify that you have read and understood the information above, that we have provided satisfactory answers to your questions and duly informed you that you are free to withdraw your consent or withdraw from the research at any time, without prejudice.

**To be filled in by the participant:**

**I have read and understood the information above and I freely agree to participate in this research study.**

**Last name, first name - Date - Signature**

You will be given a copy of this document; another copy will be kept in the file.