CER APPLICATION FORM

The CER reviews research protocols undertaken by or under the supervision of a tenured researcher or associate professor belonging to the community of research institutions of the Federal University of Toulouse.

**Project summary (one page)**

**NB** – The author of this application must delete all instructions in italics after having filled out the form. The total length of the application should not exceed 15 pages. It is recommended to condense scientific aspects to the benefit of ethical considerations and to state the issue succinctly. If the protocol is complex, combining several types of observations, a table or diagram can usefully summarize the sequences and their rationale.

#### Warning concerning the Loi Informatique et Libertés

Studies on the human person consist most of the time in the processing of personal data which requires a declaration to the CNIL and sometimes an authorization delivered by the CNIL. This aspect is not the remit of the CER, but the Committee can alert you to some issues (appropriateness of data, anonymity, “general public” tools), including in the case of studies conducted outside of France. In order to know the requirements for your study in regards to the Loi Informatique et Libertés, and undertake the prerequisite declaration formalities, we suggest you first contact the Correspondant Informatique et Libertés (CIL) of your home institution.

#### Warning pertaining to studies partially taking place outside the borders of France

*The CER does not issue any recommendation on the part of a protocol carried out outside of France and which must be submitted to a local ethics committee, or which is acquainted with the local terrain.*

### Project title:

### Scientific field:

**Tenured researcher (only 1) – project’s scientific supervisor:**

Make sure to provide all the following information: first and last name, email address, phone number, affiliation and postal address

### Other researchers taking part in the project:

**Research premises (place(s) where the study will be conducted):**

**Main objective (5 lines max.):**

**I acknowledge that the recommendation given by the CER only relates to the research project described in this document.**

**Date:**

**Electronic signature of the scientific supervisor:**

No/ Yes: e-mail:

1. **SUCCINCT DESCRIPTION OF THE PROJECT**

**Background and scientific interest**

Medical application, industrial application, importance for scientific knowledge, societal relevance, etc.

##### Your project is liable to being read by non-scientific members of the CER. Avoid or explain specialist scientific terms. Avoid acronyms.

**Aims**

**General hypotheses**

**Conflicts of interest**

To your knowledge, is one of the researchers involved in the project in a personal or institutional situation or conflict of interest with a partner, funder or any other institution? If so, please specify the character of this situation, the identity of the people involved, and if possible how the investigators intend to neutralize the interactions. A conflict of interest does not represent an a priori obstacle to a positive recommendation, but the CER is attached to situation or conflicts of interest being reported by researchers.

# EQUIPMENT AND METHODS

## Participants

### Exact number of participants or approximate "range" and criteria used to set this number:

**Recruitment**

Recruitment method: advertisement, listing, snowball sampling, etc.

Place of recruitment: specify the considered place of recruitment or the criteria which will guide the choice of the place

Selection criteria: specify the selection criteria for participants depending on your research objectives. These criteria may include age group, manual laterality, sociocultural background, education level, nationality, involvement in the process being studied, etc.

Exclusion criteria: specify the exclusion criteria for participants depending on your research objectives. These criteria are implemented after selecting participants, which means they will lead to not including in the protocol some of the selected participants. These criteria may include visual or hearing impairment, neurological disorders, addictive behaviour, etc.

Recommendations: in order to minimise privacy infringement, we recommend listing all the criteria (inclusion and/or exclusion) and asking if the participant meets all of them at once instead of asking whether he/she meets each criteria separately.

Include documents used to collect the data (example: questionnaires, interview grids…)

### Possible compensation of subjects:

Do you intend to compensate people involved in the study? If so you must state it and specify how.

## Method

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

**Equipment used:** it is important that we are clearly informed about the equipment you will use so that we can evaluate any potential risks for participants. In the particular case of EEG, indicate a preliminary test on the hand to control the absence of allergy. Specify the technical characteristics of the equipment used (audio or video recording, zoom lens…)

**Study premises:**

**Evaluations/observations schedule:** beginning and end (month and year), number of evaluation sessions on a participant, duration of evaluation on a participant. These information can be presented in a chart.

**Duration of the study:** duration of data collection

**Data analysis:** succinct description of data analysis (quantitative and qualitative)

## Predictable and known benefits and dangers for mental and physical health (self-esteem, etc.) and social life (reputation)

1. Present the benefits of your study. This can include benefits in terms of scientific developments, improvement of the quality of life of participants, of their self-esteem, etc.
2. You must answer by yes or no in the following chart in order to list the risks you may encounter during your study. In each case, you must specify how you will prevent these risks.
3. **Below the table, indicate other potential risks linked to your study.** For these and for the risks listed in the table, you must specify on a case-by-case basis the means to prevent these risks and the procedures which will be implemented if the problem actually arises (for example, if a subject starts panicking). The notion of risk covers all the constituents of the person (physical, psychic, relational, emotional, social, etc.). For example, a simple inconvenience can be considered a risk and must be listed. Special attention must be given to participants belonging to so-called vulnerable categories: inmates, children, pregnant women, etc.

Answer by yes or no in the corresponding box:

|  |  |
| --- | --- |
|  | Does your protocol include an experimental setup aimed at concealing part of the objective or methodology to subjects or make them believe in other objectives or methodologies?*If so, this application must include a description of the setup used and explain how subjects will be debriefed at the end of the study about the real objectives and methodology. Moreover, the case must be made that concealment of some aspects of the protocol to subjects is indispensable in regards with the objectives and stakes, and that none of the concealed aspects can threaten their security or their dignity.* |
|  | Questions or situations which can put participants ill at ease? |
|  | Materials which can be considered menacing, shocking or disgusting by participants? |
|  | Possibility that the participant’s private life or his/her family’s will be affected, including the use of personal information? |
|  | Use of physical stimuli (auditive, visual, haptic, etc.) other than stimuli associated with normal activities? |
|  | Deprivation of physiological needs (drinking, eating, sleeping, etc.) |
|  | Manipulation of psychological or social factors such as sensory privation, social isolation or psychological stress? |
|  | Physical efforts beyond what can be considered moderate for the participant? |
|  | Exposure to drugs, chemicals or potentially toxic agents? |

## Vigilance/Early interruption of the study

### Interruption criteria for a participating subject

Example - A subject who withdraws his/her participation consent during or after data collection.

# DATA PROCESSING – RESPECT OF THE PARTICIPANT’S PRIVATE LIFE

The project leader must specify the conditions in which collected information will be processed, de-identified and stored, along with the measures for safeguarding respect of private life during the implementation of the protocol and the dissemination of results. He/she must provide all the questionnaires used in the study or their references (in case of standardised tools), and explain how they will be administered (paper, online, interview, etc.).

## Confidentiality

### De-identification process

The notion of de-identification of data is broader than merely hiding the name. It implies that it becomes impossible to match subjects’ identity with data, even by indirect means. Generally speaking, confidentiality will be guaranteed by designating each subject or group by an identification number randomly attributed in analyses and electronic or paper documents.

However, two cases must be distinguished with regards to protection of private life and confidentiality.

**Case 1** – The protocol is such that processed data is anonymous, or de-identified using randomly assigned numbers. The person cannot be identified even indirectly and by any possible means; it is depersonalized data and no correlation table exists between each person’s identity and a random number referring to a set of individual data.

**Case 2** – Data is personal or there is a correlation table between each person and random numbers referring to a participant’s data set (a reasonable situation in view of the pursued research objectives).

In the second situation, rigorous anonymity cannot be guaranteed (people are identified or identifiable in the documents, even partially or temporarily). It must then be specified:

* why is the absence of anonymity justified
* what are the possible infringements of private life brought about by the project or the publication of its results
* what measures are implemented to face up to this risk

### People having access to data

You must specify who will have access to data: scientific supervisor, auxiliary researcher(s), etc.

## Storage

### Type of data stored (specify if identifying data, directly or by cross checking)

The CER advocates a storage duration of 15 years after data collection. In any case, a duration of 5 years is a minimum that cannot be reduced. As for storage of consent forms (necessarily identifiable), the CER advocates to store them for 10 years after the publication and 20 years if there is no publication, in a sealed envelope bearing the mention: “I certify that this envelope contains X (number) consents and X information forms, collected during the XXX study”, followed by the name of the supervisor.

**Storage premises:**

**Person in charge:**

**Possibility to destroy data upon participant’s request (see scenario in section 4):**

#  INFORMED CONSENT FORM INCLUDING INFORMATION FOR PARTICIPANTS

The application submitted to the CER must include a consent form containing the information given to participants to be signed by the subjects, and potential advertisement posters to recruit them. In case a preliminary evaluation involving tests constitutes a determining criteria for the inclusion of subjects into the study, the consent form must be signed prior to the test period.

##### Precisions on the information given to participants:

Any participant preselected will be previously informed by the scientific supervisor of the objectives of the study, of its methodology and duration, of constraints and of predictable risks. A summary of the information given by the scientific advisor will be provided in the consent form (Appendix 1).

 Generally speaking, the information given to participants in this consent must be clear, understandable and concise (avoid or explain any specialist scientific term). The document must be written in a language understood by the subject (French by default or another language if necessary. If applicable, see with the CER if a translation is necessary). Make sure to adapt the form outline suggested below to your research protocol and to the target public (for example, adaptation of the information and its presentation for children).

 The consent form must be inspired by the model below (Appendix 1). It must mention the right to refusal, the possibility of withdrawing at any time and the right to follow-up of results along with the contact details of the scientific supervisor. It will indicate to the participant that he/she is entirely free to decline taking part in the study or to withdraw his/her consent with no resulting harm (for example, when participants are students, it must be specified that refusal or withdrawal will not impact exams results. When they are patients, it must be stated that taking part in the study – refusing or withdrawing – will bear no consequence on the treatment). The possibility of rectification or destruction of his/her data will be notified to the subject. However, in the second instance, the two cases mentioned in section 3, paragraph A must be distinguished:

* Case 1 – Inform participants that rigorous anonymity makes it impossible to correct or destroy their information after completion of their participation.
* Case 2 – Inform the participants that in compliance with the provisions of the Loi Informatique et Libertés, they will be in position to exercise their right of access, and rectification or deletion with the project’s scientific supervisor.

##### Precisions on the signature and delivery to the participant of the informed consent:

After making sure the information provided is well understood, the scientific supervisor will request from the participant his/her consent to take part in the study. If he/she accepts, the participant will sign the consent form in two copies prior to the study (Appendix 1). The scientific supervisor will keep one copy and give the other to the participant.

**Specify how the informed consent will be obtained:**

For special cases such as children, persons in a vulnerable situation, persons under guardianship, please contact the President of the CER.

**APPENDIX 1 – INFORMED CONSENT AND INFORMATION FORM**

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

For example, if participants are children, make sure to explain to them the study proceedings, the possibility to quit the study at any time, etc. using a very simple vocabulary that children are able to understand. We draw your attention to the importance of adapting your vocabulary to convey information to participants (adults, elderly people, children, parents, patients, guardians) who may neither be scientists nor members of an ethics committee.

**Project title:**

**Tenured researcher – project’s scientific supervisor:**

Make sure to provide all the following information: first and last name, email address, phone number, affiliation and postal address

### Premises for the study:

**Aim of the research project:**

**What is expected from you (methodology)**

Here you must describe to the participant what he/she will have to do and in which conditions he/she will be observed.

Example – If you accept to participate in this study, you will take part in an experiment where you will match words with images. Then we will record your eyes movements while you will be listening to sentences containing the same words and choose the corresponding image (it will take about 25 minutes). At the end of the experiment, you will fill out a questionnaire in which you will provide details about your knowledge of languages and your learning of French (it will take about 5 minutes).

### Rights to withdraw from the study at any time

Mention the following aspects to the participant: 1/ His/her contribution to this study is voluntary; 2/ He/she can withdraw or stop his participation at any time; 3/ His/her decision to participate, refuse to participate, or interrupt his participation will not impact his/her grades, status or future relations with the research unit X or University Y.

### Rights to confidentiality and respect of private life

Mention the following points to the participant: 1/ The data obtained will be processed in the utmost confidentiality; 2/ His/her identity will be concealed using a randomly assigned number; 3/ No other information will be disclosed which could reveal his/her identity; 4/ All the data will be kept in a secured place and only the scientific supervisor and associate researchers will be allowed access; 5/ Concerning the possibility to destroy or rectify data a posteriori, include information as applicable based on case 1 or case 2 described in sections 3 and 4.

### Benefits

Example – The expected benefits of this study are to gain a better understanding of factors influencing the way French native and non-native speakers perceive French words. A better understanding of these factors will contribute to improving teaching methods used by teachers in French classes.

### Potential risks

With the exception of risks linked to the experimental setup which will be explained a posteriori to subjects (see section 2c), you must state here the risks which you described in the protocol and the means to prevent these risks or procedures which will be implemented if the risk arises.

Example – To our knowledge, this study entails no risk or inconvenience other than in daily life. Eye movements are recorded using a device which reflects the pupil and cornea’s infra-red light. The pupil and the cornea absorb a small amount of the energy of the infra-red light, but this energy is less than the amount allowed under international recommendations (American Standards Institute: ANSI Z 136.1-1973).

It is more or less the same amount that you receive during a sunny day.

### Diffusion

Example – This research will be disseminated through symposiums and will be published in symposiums proceedings and academic journals articles.

### Rights to ask questions at all time

Example – You may ask questions about the study at all time by writing to the scientific supervisor of the project by email at X (or by phone: Y).

### Participation consent

By signing the consent form, you certify that you have read and understood the information above, that your questions were answered in a satisfactory way and that you were informed that you are free to cancel your consent or to withdraw from this study at any moment, with no harm.

Pôle Grenoble Cognition – Comité d’Ethique pour les Recherches Non Interventionnelles (CER) (Up dated Nov 17)

### To be filled by the participant:

**I have read and understood the information above and I accept of my own free will to take part in this study.**

**First name, last name – Date – Signature**

One copy of this document is given to you, the other is kept in the record.