submission form to Paris-Saclay

|  |
| --- |
| **General information:**  The CER Paris-Saclay (CER-PS) issues directives regarding the **ethics of protocols applicable to research involving human participants**, carried out under the responsibility of a researcher, an associate professor or a research engineer **working for one of the Université Paris-Saclay laboratories.**  **To submit an application to the CER Paris-Saclay**, you will need to fill in the 4 sections of this form, and attach:   1. 1 . the participant information sheet with the right of opposition form or the **informed consent form** 2. material for the participant recruitment process (flyers, emails,..) 3. if necessary, the **questionnaires, measurement scales and grids of analysis** used for the study   **The submitted application** should not exceed a dozen pages in total, attached documents included. In this form, only the grey fields and check boxes need to be completed. We recommend providing only a summary of the scientific aspects, and focusing on **detailing the** **ethical aspects**. The submitted file should provide the information needed by the CER to **assess the quality of the information** given to the participants, the balance between the risks participants are subject to and the benefits they can gain from the study, whether the project satisfies **ethical principles** and whether people’s rights are **respected**.  If you have any questions, you can send an email to the CER Office ([cer.polethis@universite-paris-saclay.fr](mailto:cer.polethis@universite-paris-saclay.fr)) |

**Important:**

**Research involving human participants with the aim of developing biological or medical knowledge**

Research protocols involving human participants with the aim of developing biological or medical knowledge should not be submitted to the CER PS[[1]](#footnote-1), they should instead be submitted for review to a Committee for the Protection of Human Subjects (CPP) .If you are unsure as to whether your protocol can be assessed by the CER PS or whether it needs to be reviewed by the CPP, please refer to the CER federation website (in French):<https://www.univ-reims.fr/minisite_192/comment-savoir-si-on-doit-demander-un-avis-ethique-a-un-cer-ou-a-un-cpp/comment-savoir-si-on-doit-demander-un-avis-ethique-a-un-cer-ou-a-un-cpp,24565,40663.html>.

**General Data Protection Regulation (GDPR)**

Most of the time, research involving human participants requires the processing of personal data. CER- PS will not be evaluating whether your project is compliant with the GDPR, but can bring certain aspects to your attention (collecting only minimal datas , anonymity, respecting people’s rights, data confidentiality, An assessment from the CER PS does not replace advice issued by the CNIL (French Data Protection Authority). To find out about the data protection (GDPR) obligations applicable to your research, the CER PS advises you to contact the Data Protection Officer at your institution. For more information, you can go to the CNIL website (in French): <https://www.cnil.fr/fr/rgpd-passer-a-laction> or, for more specific information related to medical research, <https://www.cnil.fr/fr/recherche-medicale-quel-est-le-cadre-legal>.

**The CER PS cannot comment on research carried out beyond French borders, except in the case of these two exceptions:**

1 the country in which the research is carried out does not have its own ethics committee,.  
2 the research is carried out online, for example when a researcher employed in France uses online recruitment platforms for participants (e.g., Amazon Mechanical Turk/MTurk, Prolific) – in compliance with the GDPR.

I. Project description

*In this section, you will need to provide a description of the scientific context of the project, as well as the hypotheses of the study (1 page maximum):*

Identification of the requester (researcher, associate professor, research engineer, doctor working for University Paris-Saclay):

*Please provide the following information: first name and surname, status, affiliation and email address.*

|  |
| --- |
|  |

Title of the project:

|  |
| --- |
|  |

Scientific field of the project:

|  |
| --- |
|  |

Description of the project, including context and scientific relevance (between 10 and 20 lines)

*For example, potential applications to the health sector or to the industry, scientific contributions, potential social impact.*

***Your project may be read by non-scientific members of the CER-PS. Avoid using specialised scientific terms without explanations. Avoid using acronyms.***

|  |
| --- |
|  |

General hypotheses:

|  |
| --- |
|  |

1. Type of study:
2. *For example, (, case study, online experiments, observational studies, online survey …).*

|  |
| --- |
|  |

1. Type of data collected,
2. *For example, physiological, behavioural, or observational data, video or audio recordings*

|  |
| --- |
|  |

Conflicts of interest:

*List here any possible conflicts of interest with a partner, funding partner or any other institution, or write “no conflicts of interest”. In the event of a conflict of interest, the requester must explain how the conflict will be dealt with:*

|  |
| --- |
|  |

Place(s) where the study will be carried out:

|  |
| --- |
|  |

Period during which the study will be carried out ***(project non accepted, if the study is finished)***

|  |
| --- |
|  |

Other people participating in the project (e.g., researcher, PhD student, trainee, engineer):

*Please provide the following information: first name and surname, status, affiliation and email address.* *Please state whether each person will be in contact with participants. The people in contact with participants must have experience and training that is suitable to the people involved in the study, especially if these people are considered “vulnerable” (e.g., underage children, people with a disability, the elderly, people who are dependent on others, etc.)*

|  |
| --- |
|  |

You can, if you wish, recommend or advise against one or more reviewer(s) for the assessment of your application:

|  |
| --- |
|  |

Date:

|  |
| --- |
|  |

Requester’s digital signature (mandatory)

|  |
| --- |
|  |

II. MATERIALS AND METHODS

*In this section, you should describe the protocol and the conditions (physical and psychological) in which participants will be taking part in your study*

# A. Participants

Intended number of participants:

|  |
| --- |
|  |

Method of recruitment of participants:

*In the event that written documents are used (posters, emails, flyers, etc),* ***please attach them to your submitted application***

|  |
| --- |
|  |

Selection criteria:

*These criteria can include age range, handedness, sociocultural background, level of education, nationality, , etc. Make sure you justify these criteria with regards to the study.*

***Exercise caution in the event of existing relationships between the participant and the analyst (e.g.: student-professor, patient-doctor, employee-employer, etc.).***

|  |
| --- |
|  |

Non-inclusion criteria

*These criteria could include visual, hearing, neurological impairments, addictive behaviour, etc. Make sure you justify these criteria with regards to the study.*

|  |
| --- |
|  |

Potential payment for subjects:

*If payment applies, specify in which form and justify the amount.*

|  |
| --- |
|  |

# B. Method

Data collected, (if applicable, specify the Dependent Variables):

|  |
| --- |
|  |

If applicable: Independent Variables (provoked and/or invoked):

|  |
| --- |
|  |

Equipment and tools used:

1. *It is important that the CER-PS is clearly informed of the equipment and tools you will be using, so they can assess whether they put your participants at risk. The scales, questionnaires and grids of analysis must be included in the submitted application,*

|  |
| --- |
|  |

Procedure for the participant:

***This section is essential for the ethical assessment. Take the time to describe in detail how the study will be carried out, and specify any obligations the participants may be subject to.*** *For example: welcome procedure, task to fulfil, people present and/or in contact with the participant, methodology used with the participant dress code, etc.* ***Please specify where the study will be taking place and if necessary, describe how this place is suitable to ensure the safety and well-being of the participant.***

|  |
| --- |
|  |

# C. Expected and known advantages and risks for participants

Participant’s level of involvement:

|  |  |
| --- | --- |
| - number of sessions per participant: |  |
| - duration of each session per participant: |  |
| - time between the first participation and the last (total duration of the study for each participant) |  |

Possible advantages of your study **for the participant:**

|  |
| --- |
|  |

Foreseeable risks and constraints of your study **for the participant:**

1. *The notion of risk involves all possible risks to a human subject (physical, psychological, relational, emotional, social, etc.) Even a simple inconvenience can be considered a risk and must be mentioned. The risks described must be also explained in the informed consent form given to the participant (unless the study justifies the contrary).*

|  |
| --- |
|  |

Does your protocol involve the following:

*Please tick “****yes****” or “****no****” for the risks cited below.* ***If you tick “yes”, this risk must be included in the consent form (except for item 1)***

|  |  |
| --- | --- |
| 1/ are you using a study where part of the objective or methodology is purpose fully hidden from the subjects, or suggests other objectives or other methodology? |  |
| If you tick “yes”, justify why it is necessary to hide this information and describe what information is communicated to the subjects. Explain how this will be revealed to subjects at the end of the study, and how you will reveal the real objectives of the study. You must also explain why the information hidden from subjects does not put their safety or their dignity at risk: |  |
| 2/ are there any questions or situations that could make participants uncomfortable (privacy and/or collecting sensitive data)? |  |
| If you tick “yes”, describe how the risks in question will be minimized and/or anticipated: |  |
| 3/ does the study involve the withdrawal or modification of physiological needs (e.g., drinking, eating, sleeping, etc.) or the manipulation of psychological or social variables (e.g., depriving the senses, social isolation, physiological stress, etc.)? |  |
| If you tick “yes”, describe how the risks in question are considered and/or anticipated: |  |
| 4/ are you using any items that could be considered threatening, shocking or repulsive? |  |
| If you tick “yes”, describe how the risks in question are considered and/or anticipated: |  |
| 5/ are you using any physical stimuli (auditory, visual, haptic, etc.) that could cause any risks other than those involved in normal activity? |  |
| If you tick “yes”, describe how the risks in question are considered and/or anticipated: |  |
| 6/ does the study involve physical efforts that go beyond a level considered to be moderate (i.e., < 80% of the theoretical maximum heart rate) for a participant with an average level of fitness? |  |
| If you tick “yes”, describe how the risks in question are considered and/or anticipated: |  |
| 7/ will individuals classified as “vulnerable” be participating in the study (e.g., children or young participants, individuals with a physical or mental disability, the elderly, people who are dependent on others, etc.)? |  |
| If you tick “yes”, describe how the risks in question are considered and/or anticipated: |  |
| 8/ does the study involve the participation of hospitalised individuals and/or individuals who need regular hospital treatment? |  |
| If you tick “yes”, describe how the risks in question are considered and/or anticipated: |  |
| 9/ does the study’s effects, data or conclusions could be used by a hierarchical authority to cause an inconvenience to participants, due to their position? |  |
| If you tick “yes”, describe how the risks in question are considered and/or anticipated: |  |
| 10/ does the study involve the use of invasive methods? |  |
| 11/ does the study involve any exposure to drugs, chemicals or any potentially toxic agents? |  |
| ***If you ticked “yes” to items 10 or 11, the CER-PS cannot assess your study. It will have to be submitted to a CPP (Committee for the Protection of Human Subjects) instead.*** | |

# D. Premature termination of the study

Criteria for terminating the study for a participating subject:

1. *Specify the criteria the experimenter will need to consider, to make the decision to terminate the participation of a volunteer in the study.*
2. *As this should also be* ***included in*** *the participant information sheet, the participant can also choose to no longer participate in the study either during or after data collection, without having to justify this decision and with no resulting consequences.*

|  |
| --- |
|  |

III. DATA PROTECTION - respecting participants’ privacy

*In this section, the conditions of protecting, storing and accessing the data regarding participants and those involved in the study will be described.*

**The verification of GDPR compliance does not come under the assessments carried out by the CER-PS.**

GDPR Information:

* **If the data processed in the study is anonymous**, i.e., it is not possible to identify the people involved (removal of surnames, first names, ID number, social security number, correlation tables, etc.), even by associating stored data (for example, combining a person’s address with their date of birth), the GDPR does not apply. To check this, you can go to this website (in French): [https://www.cnil.fr/fr/lanonymisation-de-donnees-personnelles](https://www.cnil.fr/fr/lanonymisation-de-donnees-personnelles.).
* **If the data processed is not completely anonymous** (i.e., if it is still possible to identify people, for example through a correlation table), the requesting party must comply with the GDPR (<https://www.cnil.fr/fr/comprendre-le-rgpd>). Just replacing the first names and surnames of participants with an identification number is not enough to render the data anonymous: this is referred to as pseudonymization.
* **If the study requires the use of historical medical data**, the requesting party must comply with standard methodology MR004 (<https://www.cnil.fr/fr/declaration/mr-004-recherches-nimpliquant-pas-la-personne-humaine-etudes-et-evaluations-dans-le>)

**Is your study concerned by the MR004?**

Yes

No

# A. Privacy

Data protection procedure:

1. *Provide details about the data protection procedure used to ensure that data is not disclosed, deleted or modified, either by mistake or by an unauthorised person (anonymisation, pseudonymization, IT security measures, passwords, physical security measures, etc.).*
2. *The notion of data anonymisation is much wider than just preventing the disclosure of the participant’s name. It also implies that the researcher cannot link the identity of subjects to the data, even through indirect means (for example with a correlation table which would be stored by a doctor). Most often, we speak of pseudonymization.*

|  |
| --- |
|  |

People who have access to the data:

*You must specify who will have access to which information (e.g., lead scientist, research associate(s), data transferred to other organisms, etc.). If data is to be transferred, specify which procedure is used to ensure secure data transfer.*

|  |
| --- |
|  |

# B. Archiving

Types and formats of archived data:

*E.g.: Consent form in paper format, physiological measurements in electronic format, etc.*

|  |
| --- |
|  |

Archiving period:

*For patient data, the UREC advises that this data is archived for a period of up to two years after the last publication of the research results, or, in the event that the results are not published, up until the signature of the final research report.*

|  |
| --- |
|  |

Archiving location for each type of data:

|  |
| --- |
|  |

Person responsible for archiving:

*The person responsible for archiving must be a permanent member of staff*

|  |
| --- |
|  |

# C. Rights over personal data

How will you ensure that people can easily exercise their right to access, rectify and remove their personal data?

*Specify to whom this request should be made, and with which means. The CER PS recommends facilitated contact, for example directly with the project leader.*

|  |
| --- |
|  |

Have you planned something for people to be able to ask questions about the processing of their data throughout the project, and to give them access to the overall results for the project?

|  |
| --- |
|  |

IV. Gathering the PARTICIPANT information SHEET OR, IF REQUIRED, A Consent form

***Please note that the participant information sheet or consent form must be included in the file submitted.***

Have you arranged for participants to be provided with an information sheet with the right of opposition, or to ask for participants’ consent?

*Specify why you made this decision*

*It may be mandatory to ask for informed consent from people before carrying out any research that involves human subjects.* ***Some projects are an exception to this principle, for example (1) when the research is carried out on historical data or (2) when the research involves minimal risk for participants and/or (3) when the research cannot be carried out correctly if informed consent is required.***

|  |
| --- |
|  |

Details about how participants will be provided with this information or how informed consent will be collected (if required):*(Internet, paper, etc.)*

|  |
| --- |
|  |

In the event that data is collected from underage subjects or subjects who are legally protected, specify how these people will be informed or, if required, how their agreement (underage subjects) or consent will be acquired:

|  |
| --- |
|  |



**Check-list of documents to provide along with this file:**



Completed submission form

Informed consent or participant information sheet with the right of opposition



Participant recruitment documents (posters, emails, flyers, etc.)



If necessary, questionnaires, scales, grids of analysis

**In the case of studies that are carried out outside of France, the Paris-Saclay CER PS can still give an advice in the following cases:**



The country in which the study is carried out does not have its own local ethics committee



The research is carried out online and involves participants who are not French, for example using platforms such as Amazon Mechanical Turk, etc. This research must be compliant with the GDPR.

1. Information about research involving human participants (in French):

   <https://ansm.sante.fr/var/ansm_site/storage/original/application/593719f11ffe1550a91c4bd0a475ca2e.pdf>

   <https://www.anrs.fr/sites/default/files/2019-07/GDP_POS_07F_MO_01F-Typologie_V3.0_10072018_0.pdf> [↑](#footnote-ref-1)