What are the most common grounds for a conditional opinion or non-approval of research projects by CEEP?	**How can I overcome these difficulties?**
Informed consent has missing Essential Information. It is very common that the informed consent form initially submitted does not contain all the essential information necessary for such a form.	The informed consent form should be concise but complete. CEEP makes available on its website standard forms for informed consent for studies where personal data are expected to be collected and for those where no personal data will be collected. Please adapt your informed consent form from these templates. Prepare the informed consent form. Then compare it with the *checklist* of essential information that it must contain as shown in the submission form. It is essential that this form contains the following information: — the researchers in charge of the study (including the name of the mentor) and the host institution, — the purpose of the study, — the study population, — what participants have to do to participate and how long they have to participate, — how the data (personal or other) will be stored and processed, and how long it will be stored, — anonymisation procedures, where applicable, — potential risks, adverse effects and unexpected outcomes arising (although not significant and unlikely) and ways to mitigate them, — the voluntary nature of the study, — contact details if the participant wishes to ask questions or comment on the study. **The informed consent form (or *debriefing*) is written in a technical language that is**

*Translation into English: EU eTranslation tool

not accessible to all potential participants. Sometimes, informed consent forms are written in excessively technical language that may not be understood by all people in the study population. For example, the purpose of the study is indicated as it should be formulated in the scientific report reporting the results (e.g. “Mediating effect of...”). Informed consent must be clear and written in such a way that it is well understood by all potential participants.	Avoid technical and scientific jargon. Use short sentences. Give informed consent (or *debriefing*) to read someone who is not proficient in the research topic and who has a lower level of education, and ask them to summarise what they have read using their own words. This is a good way to ensure that informed consent has been understood by the individual. The sentence or idea where there is hesitation needs to be rewritten.
There are non-conformities or discrepancies between what is described in different parts of the submission form, or between it and the informed consent form or other document submitted for consideration. Or parts of these documents are not clearly written.	Please review all documents before submitting them. It may sometimes be useful to print the documents and read them with a pencil in the hand, marking the points where there are discrepancies and inconsistencies. The phrases you hesitate or need to reread probably need to be rewritten to make them easier to understand.
The submission form states that no procedures are foreseen to confirm the understanding of the content included in the informed consent form, as participants will be fluent in the language in which the informed consent will appear.	Regardless of the native language of the participants or the languages in which they are fluent, initiatives should always be promoted to ensure that the participants understand all content of the informed consent form and study procedures. If the collection of informed consent and/or data is individual and face-to-face, they may, for example, ask potential participants to summarise, using their own words, the content of the informed consent; or (b) ask potential participants if they have any questions or questions about the

content of informed consent and study procedures before signing informed consent. In cases where data collection takes place in a group, and the correct clarification of informed consent also takes place in a group, the suggestion in (b) could be adopted.

There are greater difficulties in collecting informed consent via online forms (e.g. Googleforms, Qualtrics). In such cases, it could at least be reinforced in the informed consent form that potential participants should contact the investigator, before agreeing to participate in the study, to clarify any doubt or issue regarding the content of the consent that may persist.

In studies with participants under 18 years of age, informed consent is collected from the parents or legal guardians of the potential participants, whether the data collection takes place in person or not. In such cases, a procedure similar to that adopted in studies where informed consent via online forms should be followed, and the consent of the participating minor should be guaranteed in all cases.

The risks associated with participation, and potential significant adverse effects or unexpected outcomes, even if unlikely, are not correctly identified in the submission form, informed consent form and *debriefing*.

There are studies that – by their nature, theme or population – deserve particular attention with regard to potential significant risks, even if their occurrence may be unlikely. Whenever we work with vulnerable populations (*see* submission form for examples of vulnerable populations), or there are significant risks (*see* form from submission for examples of significant risks), this information should be clearly provided in the informed consent form and *debriefing*, active monitoring of adverse effects and unexpected outcomes should be promoted and reported to CEEP at all times, and the means of mitigating and managing these adverse effects should be detailed. Because of paragraphs 9 and 16 to 18 of the Helsinki Declaration, the procedures for mitigating and managing these should go beyond providing free community service contacts (e.g. SNS24 Psychological Support Line). Liability for the damage caused by the investigation shall not be transferable to the participant – even if he or she has been informed of the risks – or to third parties. You can consult the monitoring and risk management flowchart provided by CEEP as an annex to this document.

There are no significant risks, and adverse effects and unexpected outcomes are very unlikely, and no monitoring and risk management procedures and possible adverse effects and unexpected outcomes are identified in the submission form, informed consent form and *debriefing*.

There are studies that – by their nature or scope – can cause temporary psychological discomfort, even if unlikely and insignificant. The procedures proposed by the research team to protect participants from possible risks and unexpected adverse effects, even if minor and temporary, will be analysed by CEEP on a case-by-case basis. CEEP suggests, however, that in such cases the investigation team should include this information in the informed consent. In addition, the investigation team should make it possible to monitor their occurrence (e.g. increase in *debriefing* the possibility of contact with investigators in the event of any psychological discomfort associated with participation). If adverse effects, even mild and transient, are observed and reported to the investigation team, they should be reported by the investigation team to CEEP. In addition, free community service contacts (e.g. SNS24 Psychological Support Line) should be offered in the *debriefing*.

It is not made explicit how long the data will be stored or whether anonymised data will be made available in a repository.

In the case of personal data (e.g. name, telephone number, email address, voice registration), a maximum retention period should be observed. These should be up to 6 months after the public test, in the case of dissertations and theses, after which they should be destroyed. In studies where *master lists are used* containing both an identifier of the participants (e.g. alphanumeric code identifying each participant) and some personal data, the same maximum retention period of the *master list* should be observed, after which the master list should also be destroyed.

As the data are collected anonymously, the Code of Conduct on Ethics in Research stipulates in relation to data storage that “All data collected in the context of research must be stored and maintained in a secure and accessible manner, for a period of at least 5 years from the end of the study/project or, if reported in scientific publications, from the date of the original publication” (point 3.31.), and that “At the end of the storage period, any deletion or destruction of the data must be done by

Agreement with the applicable ethical and legal requirements, with special regard to the general principles of confidentiality, protection and security of the participants" (point 3.33.). Informed consent shall be formulated with an indication that anonymous data will be stored and maintained in a secure and accessible manner for a period of at least five years from the end of the dissertation or, if researchers plan to report results in scientific publications, from the date of the original publication.

To adhere to open science practices, anonymised data could be shared with the scientific community.

In case the research team chooses to make anonymous data available in any open public repository, it will be important to add this information. In the latter case, it will not be necessary to indicate the period for which the data will be stored. This information may be accompanied by an indication that these are transparency practices in research aimed at facilitating the replicability of scientific results.

The submission form states that it is an anonymous data collection. This will be done online, but it is not indicated what procedures will be put in place to ensure that no data will be collected that will allow re-identification, such as IP and geographical location.

To ensure anonymity during the collection of information, CEEP recommends that researchers make sure that anonymisation is activated in Qualtrics, so that it does not include location information and IP address. To do so, on the project homepage, you should open the field "Survey options" and click OK under the option "Security – Anonymise responses"
