# INFORMED CONSENT GUIDELINES

1. **For studies that <u>do not</u> involve the processing of personal data of the participants**
2. **For studies that involve the processing of <u>personal data of participants</u>**

**Preliminary note:**

Informed consents are drafted based on the principle of transparency, as explained in the General Data Protection Regulation (GDPR).

**Informed consent should include:**

- Information on the study concerned: scope and objectives;
- Information on those responsible for the study, indicating their affiliation and contact details;
- Clarification on data collection measures/methods;
- Explain inclusion requirements/criteria (e.g. minimum age);
- Clarification on possible compensation (e.g. financial, credits);
- Explanation on contributions (e.g. benefits of the study for society, for understanding a phenomenon), potential risks, and respective mitigation measures;
- Explanation on the voluntary nature of participation and information on the right to interrupt/right to withdraw at any time;
- information on the estimated duration of participation;
- information on data anonymization and confidentiality, indicating how the data collected will be processed and stored;
- The consent must end with a section where the participant declares that he/she has understood the nature of the study, the request made to him/her and other information previously explained;
- In paper-based studies, the participant must sign his/her consent form, indicating the date on which he/she received it; In online studies, there should be a specific field where the participant declares/confirms his/her decision to participate;
- For vulnerable populations, a declaration of assent should be provided;
- It is suggested that the participant be given the possibility to keep a copy ("duplicate") of the consent form in his/her possession, while the original remains with the study submitter.
- If you include personal data, please consider the existing indications/guidelines for this purpose (see next point)

**Note:** It must be ensured that the language fits the target population.

**EXAMPLE OF INFORMED CONSENT**
**WHERE THE PROCESSING OF PERSONAL DATA DOES NOT EXIST**

## INFORMED CONSENT

This study is part of a research project being carried out at **Iscte – Instituto Universitário de Lisboa**, (if *funded, please indicate the funding entity and its references*). The aim of the study is (*briefly and clearly describe the objective).*

The study is being carried out by (please *indicate the researcher's name of the and his/her e-mail address*), whom you can contact if you have any questions or comments.

Your participation in the study, which will be highly valued, as it will contribute to the advancement of knowledge in this field of science, consists of (*briefly and clearly describe the type and duration of the tasks to be performed by the participant*). No significant risks are expected in association with participation in the study (if *any, specify them and describe what measures have been taken to mitigate/control their effects*).

Participation in the study is strictly **voluntary**: You can freely choose to participate or not to participate. If you have chosen to participate, you can interrupt your participation at any time without having to provide any justification. In addition to being voluntary, participation is also **anonymous** and **confidential.** The data collected is solely intended for statistical analysis, and no responses will be analyzed or reported individually. At no point in the study will you need to be identified.

I declare that I have understood the objectives of what was proposed and explained to me by the researcher, I was given the opportunity to ask all and any questions about this study, and all of them have been answered satisfactorily, so I **accept** to participate in the study.

_____, _____ / ____ / ___

[place, day / month / year]

**Name:**

**Signature:**

**(IF YOU ARE NOT YOUR OWN SIGNING ON AGE OR INCAPACITY REASON,** *Cf. Articles 7 – "Minor participants" – and 8 – "Major participants unable to give informed consent" – of Law No 21/2014 of 16 April*2014 )

(If *the child is able to understand, he/she/they must also sign the document, expressing his/her/they consent*)

(if *you are a relative, indicate the degree of family relationship, bearing in mind that the authorization must be signed by the legal representative/guardian, who may not be a parent or other relative*)

**Name:**

**Identification document No:**
**Date or validity:**
**Legal representative:**
**Signature:**

**EXAMPLE OF INFORMED CONSENT**

**WHERE PERSONAL DATA PROCESSING EXISTS**

The guidelines on informed consent when personal data is processed, follow the general guidelines of ISCTE and are available HERE.

This study is part of an ongoing research project at Iscte – Instituto Universitário de Lisboa, *(if funded, please indicate the entity and its references).*
The study aims to _____ *(briefly and clearly describe what the objective is).* Your participation in the study, which will be highly valued, will contribute to the advancement of knowledge in this field of science, consists of *(succinctly and clearly describe the type and duration of the tasks to be carried out by the participant).*

Iscte is responsible for the processing of your personal data, collected and processed exclusively for the purposes of this study, having as a legal basis your consent *(indicate article 6, no. 1, a) and / or article 9, no. 2, a) of the General Data Protection Regulation, as applicable).*

The study is carried out by _____ *(indicate the name of the researcher and his/her address e-mail),* whom you can contact if you wish to clarify a question, comment or exercise your rights regarding the processing of your personal data. You can use the indicated contact to request access, rectification, erasure or limitation of the processing of your personal data.

Participation in this study is **confidential.** Your personal data will always be processed by authorized personnel, bound by the duty of secrecy and confidentiality. Iscte ensures that appropriate techniques, organizational and security measures are in place to protect personal information. All personnel involved in the study is required to keep personal data confidential. In addition to being confidential, participation in the study is strictly voluntary: You can freely choose whether, or not, to participate.

If you choose to participate, you may stop participation and revoke your consent for the processing of your personal data at any time, without having to provide any justification. The withdrawal of consent will not affect the legality of any processing carried out prior to the withdrawal based on the consent provided.

Your personal data will be kept by _____ *(specify duration, criteria or the* point in *the study when they will be anonymized or destroyed),* after which they will be destroyed or anonymized, ensuring their anonymity in the study results, only disclosed for purposes such as teaching, communication at meetings or scientific publications.

There are no significant expected risks associated with participation in the study *(if any, specify what are they and what measures have been taken to mitigate/control their effects)*.

Iscte does not divulge/disclose or share, with third parties, the information relating to your personal data. *(in case of subcontracting or if you wish to share data with other research teams or studies, add: In some cases, the research team may share data with other research teams, or service providers acting under our guidance and responsibility. In this study, personal data are disclosed to the following entities:*
*• identify researcher / research team / or service provider).*

*(in case of transfer of personal data to a third country or an international organization outside the European Economic Area, include this information and indicate whether or not there is an adequacy decision adopted by the Commission; in the absence of an adequacy decision, information should be included on the risks that may arise for participants and the measures taken to mitigate them) (in the event that the processing of personal data involves automated decision-making, including profiling, as referred to in Articles 22(1) and 22(4) GDPR, include useful information regarding the logic involved, as well as the significance and the envisaged consequences of such processing for the participant).*

Iscte has a Data Protection Officer, who can be contacted at mailto:dpo@iscte-iul.pt. If you consider it necessary, you also have the right to lodge a complaint with the competent supervisory authority – the National Data Protection Commission.

**I declare that I have** understood the objections of what has been proposed to me and explained by the researcher, that I have been given the opportunity to ask all the questions about this study and that all of them have received an enlightening/satisfactory answer.

**I agree** to participate in the study and consent to the use of my personal data in accordance with the information made available to me.

**Yes ☐ No ☐**

_____, _____ / ____ / ____ [place, day / month / year]

**Name:**
**Signature:**

**(IF YOU ARE NOT YOUR OWN SIGNING ON AGE OR INCAPACITY REASON,** *Cf. Articles 7 – "Minor participants" – and 8 – "Major participants unable to give informed consent" – of Law No 21/2014 of 16 April*2014 )

(If *the child is able to understand, he/she must also sign the document, expressing his/her/they consent*)

(if *you are a relative, indicate the degree of family relationship, bearing in mind that the authorization must be signed by the legal representative, who may not be a parent or other relative*)

**Name:**

**Identification document No:**
**Date or validity:**
**Legal representative:**
**Signature:**