Guide on the ethical aspects to be assessed in research projects involving people and personal data

Joan Canimas Brugué and Anna Bonmatí Tomàs

1st edition (2021)

Universitat de Girona

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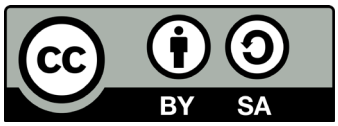

Edited by: Servei de Publicacions – Universitat de Girona

ISBN: 978-84-8458-603-6

Girona, April 2022

INTRODUCTION

Ethical and scientific excellence in research requires a particular ethos from all those involved, in terms of the way they behave and respond, in addition to a staunch commitment to human rights and values and the scientific method.

When planning research work, it is necessary to identify and respond correctly to the ethical matters posed by the project, which must be reflected in the research protocol chapter dedicated to ethical aspects.

This Guide seeks to help researchers in their pursuit of ethical excellence in studies in which they invite people to participate. Furthermore, the aim is for it to serve as a Guide for assessors and members of the Research Ethics Committees (CEI).

— Chapter I, *Research Ethics Committees* introduces the different types of committees and provides indications as to their duties, composition and commitments.

— Chapter II, *Aspects of the research protocol to be assessed* provides details of the ethical aspects to be taken into consideration and assessed as part of the planning and execution of a research project.

— Chapter III, *Aspects of informed consent and informed authorisation documents to be assessed* explores the ethical aspects that must be included in informed consent and authorisation documents.

— Finally, the appendices include: *(i)* a Rubric to facilitate the ethical appraisal of research projects. Each item corresponds to the guideline set out in this Guide using the same number; *(ii)* references and links to ethical and scientific good practice codes and protocols, and *(iii)* references and links to laws cited in the Guide and others that may be of interest.

We would like to thank the members of the Research and Biosafety Ethics Committee at the University of Girona for their feedback and contributions, in particular Josep

Matas Balaguer and Maria Pla de Sola Morales. This Guide, like all guides, is a living document that will be updated regularly to incorporate improvements. Therefore, please feel free to send any feedback or comments you may have to us, at either joan.canimas@udg.edu or anna.bonmati@udg.edu.

RESEARCH ETHICS COMMITTEES

I. Types of research ethics committees

There are different types of research ethics committees, depending on the research project subject and field to appraisal. There are research ethics committees in the field of health, research ethics committees with medicines, ethics committees at universities and public authorities, animal experimentation ethics committees, etc.

If the invitation to participate is conducted as part of the health services, the project must be assessed by the Research Ethics Committees accredited in this field (CEIs)[1] or the Research Ethics Committees with Medicines (CEIm). Research affecting or likely to affect individuals that is carried out outside the health care setting, without any medical technique or treatment or the use of any medicinal product or medical device, shall be assessed by the ethics or bioethics committees at universities (if the principal researcher is from the university sector) or the ethics committees of public authorities (if the principal researcher is not from the university sector). At present, the ethics committees of public authorities are yet to be created; therefore, it is often universities who appraise these research projects, usually on the basis of a collaboration agreement.

II. Appraisal procedure

Each CEI must adopt and regulate the assessment procedure that best suits its characteristics and those of the organisation it belongs to, the type of number of projects assessed, the resources available, the time its members dedicate, etc. Furthermore, the procedures are dynamic and may vary temporarily to adapt to the needs at any given time. An example of this can be seen in the situation created by the

[1] Research Ethics Committees for health services, as the first to be established, are identified using this generic name and the acronym "CEI". However, there are now ethics committees that appraise health projects not undertaken in the health sector (for example, those conducted at universities) or that appraise other types of project, for example, human or social sciences. In light of this, in this Guide we have chosen to use the term Research Ethics Committee (CEI) to refer to any committee whose function is to appraise the ethical aspects of a research project. When necessary, we have distinguished between the two by adding a letter to the end: CEIs (for health) and CEIm (for medicines).

SARS-Cov2 pandemic: the increase in the number of research projects has seen many CEI meet more often.

CEI committees usually comprise ten to fifteen members, with training and experience in the different areas of research being reviewed (health sciences, biological sciences, social sciences, etc.) and training in ethics and law applied to research. Furthermore, there must be at least one expert in ethics applied to research, another in law, another in data protection and another in research methodologies. When necessary, experts in the matters considered relevant to the appraisal must be present, or their advice sought, when members of the CEI have no prior knowledge of the matter. The range of experts and professionals facilitates an objective analysis and enriches the debate.

CEI committees usually meet once per fortnight or month in plenary sessions, in other words, at which all members are present. Some CEI hold regular or extraordinary meetings via so-called emergency or permanent committees, consisting of a reduced number of committee members. These subcommittees offer final approval to projects that had already been validated at the plenary session, but for which the researchers had to make small amendments (favourable report pending minor changes) or assess urgent research projects with a view to the researchers introducing the corresponding amendments before the plenary session.

To speed up the process, some CEI have all research projects assessed before the plenary session by one or two assessors, who may belong to the CEI itself or one may be external, for example, a specialist in the subject being assessed. Whenever amendments are necessary, the researcher is informed so that they can be introduced before the plenary session. These assessors are responsible for submitting their assessment, which is not binding, at the plenary session.

Once the research project has been assessed, the CEI issues a ruling, which may be favourable, favourable pending minor changes, or unfavourable. It may also request any clarifications considered necessary to issue a ruling. Ideally, the ruling should be the result of a consensus among all members of the CEI, although there may be dissenting votes.

The members of the CEI are bound by professional secrecy in compliance with data protection regulations and also to preserve other rights, such as intellectual and

industrial property rights and business secrecy. This obligation is recalled and reinforced by the signing of a confidentiality document.

III. Monitoring and control of research with a favourable ruling.

CEI committees are not only required to supervise research protocols, they are also required to establish control procedures to ensure that the research they have validated is compliant in practice. The bigger the risks and disturbance to the project foreseen, the stricter the monitoring and control mechanisms should be. However, the means to do this are not yet available, especially in terms of human resources. In this regard, and as established in point 3.8, the researchers shall commit to undertaking the research as indicated in the documentation submitted and any significant change shall be communicated to the CEI.

Furthermore, the document containing the favourable ruling issued by the CEI shall indicate the responsibility of the researchers to conduct the research as indicated in the documentation submitted and that any significant change must be communicated to the CEI, requiring a new appraisal.

RESEARCH PROTOCOL. ASPECTS TO BE ASSESSED

IV. General aspects

(1) Documentation to be submitted to the CEI.

(1.1) Total or partial validation of a research project.

Often, a CEI will assess projects that include the entirety of a line of research (total assessment). However, some projects are organised into consecutive phases, regarding which the researchers cannot provide the details required by the CEI for the purposes of the validation process (for example, the questions to be asked as part of an in-depth interview), as they first need to access the results and assessment of the previous phases (partial assessment).

As part of multi-centre research projects in which the general project has been assessed and validated by another CEI, consideration is given to whether the protocol should also be assessed by the CEI from whom the partial validation is being requested. We believe that the protocol should be assessed, as it is necessary to see the part as part of the whole, not just to facilitate understanding, but more importantly because this part may be ethically correct but form part of a whole that is not. During this assessment process, objections to the general project may arise that were either not detected by the other CEI or that could not be detected, as they were added at a later date to adapt the protocol to the new phase of research.

(1.2) Documentation to be submitted for total assessment.

For an entire research project to be assessed, the CEI must be provided with the following documentation:

(i) Protocol of the research project, with at least one chapter devoted to ethical aspects.

The research protocol shall contain at least one chapter or section on the ethical aspects to be considered as part of the research.

(ii) Ethical self-assessment document.

It is highly recommended that the researchers submit an ethical self-assessment document in relation to the research project. This helps to improve its ethical quality and makes it more likely that a favourable ruling will be issued by the CEI. This Guide is accompanied by a Rubric that can be used to this end.

(iii) Informed consent document or documents for the participant, as applicable.

With very few exceptions (see points 14 and 15 on anonymity and journalistic or sociological research), informed consent is required from the individuals participating in the study, their legal representatives or the organisations conducting the research (see points 10 and 11 on consent and informed authorisation).

(iv) Informed authorisation document or documents for the organisation, as applicable.

(v) Short financial report, as applicable.

As applicable, the protocol shall include a section on the financial aspects of the research project or a brief attached report (see point 31 on financial or similar remuneration).

(vi) Data Protection Impact Assessment (DPIA), as applicable.

When data processing poses a high risk to individual rights and freedoms, a Data Protection Impact Assessment (DPIA) must be submitted, in addition to the safety measures identified to reduce this impact (see point 25).

(vii) Any other documentation that may be relevant.

Any other documentation that may be relevant to the assessment of the research project shall be included. For example, surveys, questionnaires or tests administered.

All documentation shall be submitted appropriately, well organised and in an easily distinguishable way.

(1.3) Documentation to be submitted for partial assessment.

For one or more phases of a research project to be assessed, the CEI must be provided with the following documentation:

(i) Research project protocol.

If the protocol has already been approved previously by the CEI and non-significant changes have been made, the changes from the previous version shall be highlighted in a different colour. When significant changes are made, the entire protocol must be assessed again.

(ii) Partial protocol of the phase or phases for which CEI assessment is being requested.

The partial protocol for which assessment is being requested must be easily recognisable (for example, an appendix or as part of the same protocol, but duly highlighted).

(iii) Scientific justification for it being impossible to provide the necessary information for the ethical assessment of all phases of the research project, meaning that a partial assessment is necessary.

(iv) Ethical self-assessment (for example, the Rubric accompanying this Guide).

(v) Informed consent document or documents for the participant, as applicable.

(vi) Informed authorisation document or documents for the organisation, as applicable.

(vii) Short financial report, as applicable.

(viii) Data Protection Impact Assessment (DPIA), as applicable.

(ix) Any other documentation that may be relevant.

(1.4) Corrections made after an assessment by the CEI.

With a view to facilitating the CEI assessment, the changes that the CEI asks to make to the documentation submitted for the new assessment:

(i) Shall be introduced in the same documents submitted previously and in a way that makes them easily identifiable (for example, in a different font colour).

(ii) In the Rubric and corresponding box (*Researcher's observations*), it shall be indicated that the requested change has been made or , if applicable, respond to the request made or make any appropriate observations (for example, why they believe the appraiser has not correctly understood the matter in question).

(2) Scientific validity of the research project and the necessary aptitudes and conditions of the research team to conduct the research.

The first condition that must be met by a research project is its scientific quality: it must be scientifically justified (which includes offering new knowledge) and well thought out, and the principal researcher and, if applicable, the research team, must have the necessary aptitudes and conditions to conduct the research**.** Demanding the attention of the participants, subjecting them to discomfort or risks and dedicating resources to research is only acceptable when it has been well thought out.

A CEI does not assess the scientific and methodological quality of a research project or the aptitude of the researchers and resources to undertake it, rather it assumes that these conditions are in place. Research projects must, therefore, either be assessed before by a Scientific Committee or be secured by a guarantee provided by the principal researcher(s). This does not mean that the CEI cannot warn, communicate or condition its ruling on matters relating to the scientific or methodological quality of the research project appraised or the resources used to undertake it.

However, scientific excellence alone is not enough. Research must also guarantee ethical excellence, as on occasion knowledge has fallen or falls into the wrong hands or fails to take into consideration the harm it causes or helps to cause.

(3) Ethical principles and commitments demanded from the researchers.

Not only do the researchers need to have the scientific aptitudes and necessary material conditions to undertake the research, they must also have an ethical commitment.

The research protocol must contain at least these eight commitments by the researchers:

(3.1) Ethical and scientific good practice.

According to the guidelines of ethical and scientific good practice in the European Code of Conduct for Research Integrity (2018), there are four main principles when it comes to research integrity:

> "Reliability in ensuring the quality of research, reflected in the design, the methodology, the analysis and the use of resources.
>
> Honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way.
>
> Respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment.
>
> Accountability for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts."

Any of the other codes may also be mentioned (see Appendix 1).

(3.2) Commitment to confidentiality and professional secrecy, compliance with good ethical practices and the provisions of Regulation (EU) 2016/679 (RGPD) [2] and Organic Law 3/2018 (LOPDGDD)[3].

If personal data (not anonymous data [4]) are processed (obtained, processed, transmitted or stored) , the researcher shall commit to maintaining confidentiality and professional secrecy and complying with

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[2] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons regarding the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (hereinafter General Data Protection Regulation or GDPR). https://www.boe.es/doue/2016/119/L00001-00088.pdf.

[3] Organic Law 3/2018 of 5 December on Personal Data Protection and the guarantee of digital rights (hereinafter LOPDGDD). https://www.boe.es/buscar/doc.php?id=BOE-A-2018-16673.

[4] As will be seen in point 22 on obtaining and processing anonymous data, the law distinguishes between *information* and *personal data*. Personal data is any information about an identified or identifiable natural person and, therefore, information is always anonymous and becomes personal data when it is possible to identify the person or persons they refer to. In this Guide, however, the terms *anonymous data* and *personal data* will be used and when referred to indistinctly, the term *data* shall be used.

the best ethical practices and provisions of the GDPR and the LOPDGDD. These two rules, as well as the rules further developing them and guides for their correct implementation, can be consulted at the Spanish Data Protection Agency (www.agpd.es) and the Catalan Data Protection Authority (https://apdcat.gencat.cat/ca/inici/).

(3.3) Commitment to confidentiality and professional secrecy regarding research procedures and results.

Researchers not only have duties of confidentiality and professional secrecy towards the persons participating in the research, but also to research team members and sponsors. They may not disclose information about procedures, achievements, difficulties, research results, etc. without authorisation or following established guidelines.

(3.4) Submitting a new request for a favourable ruling from the CEI when there are significant changes in the research conditions or procedures.

(3.5) Publishing the research results or making them public.

The research results must be published or made public, including when the expected results are not obtained, with a view to ensuring that the same research is not conducted again under the same terms. Dedicating resources or requesting the involvement of people in research that has already been conducted, without serving any new purpose, is something that should be avoided.

(3.6) Whenever possible, informing participants, when they have given their consent for doing so, that the research has been completed and informing them of the publication of the results or how to access them.

As far as possible, those invited to participate in a research project shall be informed of how they can access the results of the study once they have

been made public[5]. If personal data (an email address, telephone number, etc.) is necessary to this end, they shall be informed that this data will be stored pursuant to the legislation in force and only used for this informational purpose, and will subsequently be destroyed.

(3.7) Informing the CEI that the research has been completed and informing them that the results have been published.

Once the research work is complete, the principal researcher shall inform the CEI of this, in addition to the location where the results have been published.

(3.8) Being familiar with the research protocol assessed by the CEI, conducting research according to its content, and complying with the ethical commitments and obligations established therein.

(4) Research outside the European Union.

Research that involves any phase conducted outside the European Union:

(4.1) Shall meet at least the same ethical and legal quality criteria as established in the European Union.

It shall meet the same ethical and legal quality criteria as research conducted in the European Union and as set forth in this Guide and established in the legislation in force.

[5] In this regard, the last paragraph of Article 26 of the World Medical Association Declaration of Helsinki (1964/2013) states: "All persons participating in medical research should have the option to be informed about the overall results of the study."

(4.2) If the quality standard of the country or countries is higher than that of the European Union, it must be implemented.

When the ethical and legal quality criteria in the country in which the field work is being conducted is more demanding than the criteria established in this Guide and in EU and Spanish law, this shall be reflected in the research protocol and the research protocol guidelines shall be replaced or complemented by those offering a higher level of quality and guarantees, which shall be met throughout the entire research process (not only the work conducted in said country).

International data transfers to recipients established in countries outside the European Economic Area (the EU countries plus Liechtenstein, Iceland and Norway) shall follow the provisions of European legislation on data protection[6].

V. Harm, risks, discomfort and benefits.

(5) Not causing harm, minimising risks and discomfort and generating benefits.

(5.1) Harm, risks and discomfort.

The Hippocratic principle *primum non nocere* (first, do no harm) is morally applicable to all research projects. However, the absence of harm is not sufficient in guaranteeing respect for those participating in a study. The risks and discomfort (coercion, discomfort, fear or any minor and temporary disruption to well-being or peace of mind), in particular in relation to those deemed vulnerable, must be weighted.

At present, not causing harm shall apply not only to those currently alive, but to future generations. The rights and well-being of future generations must be preserved, as must their right to living on Earth with the

[6] To this end, consult the website of the Spanish Data Protection Agency (https://www.aepd.es/es/derechos-y-deberes/cumple-tus-deberes/medidas-de-cumplimiento/transferencias-internacionales).

biological and geological diversity inherent to the planet, with a healthy environment and a peaceful society[7].

A key but by no means easy aspect of certain research is determining the level of risk and discomfort to which participants will be subject, which must be identified and explained in the research protocol and assessed by the CEI. In terms of research, we define risk as the probability of suffering harm, loss, injury or other adverse consequences, whether physical, psychological (negative affects, changes in conduct, anxiety, blame, sense of uselessness, fear, anger, etc.), moral or social (stigmatisation, change in the relationship with others, embarrassment, loss of respect, etc.), legal (risk of discovery and judgement) or economic (loss of employment, or access to the benefits of an insurance policy, etc.)[8]. Although the literature does not often address discomfort, we believe doing so is necessary to define the level of impact between what we consider risk and the absence of any disturbance. For example, if a person has to stop working on account of their participation in the research, this is not a risk, but it is a discomfort.

The scale proposed is as follows[9]:

RISKS	DISCOMFORT
High	High
Medium	Moderate
Low	Low
Non-existent	Non-existent

[7] Hans Jonas, in *Das Prinzip Verantwortung* (1979), warned that developing technology required ethics not only in relation to those already alive, but also to future generations, and described in multiple ways the need to consider the happiness and misfortune of future generations in the form of these imperatives: "Act so that the effects of your action are compatible with the permanence of genuine human life", "Act so that the effects of your action are not destructive of future possibility of such life", "Act not destructively for future generations and the totality of their life conditions", and "In your present choices, include the future wholeness of Man among the objects of your will" (Jonas, H. (1979): *Das Prinzip Verantwortung: Versuch einer Ethik für die technologische Zivilisation*. Translated into Spanish by J. M. Fernández: *El principio de responsabilidad: ensayo de una ética para la civilización tecnológica*, Barcelona: Herder, 1995).

[8] Aarons, D.E. (2017). "Exploring the risk/benefit balance in biomedical research: some considerations". Rev. bioét. (Print). 2017; 25 (2): 320-7.

[9] Ibid.

If risks and discomfort are foreseen, both in the research protocol and the informed consent document, they must be identified and clearly and accurately explained, and alerts and reactions indicated (for example, civil liability insurance).

(5.2) Benefits.

As part of the scientific justification of the protocol, the benefits expected in terms of knowledge for society in general or a particular group of people must be identified. It will also be necessary to establish whether the participants are expected to see any benefits and, if so, the type of benefits. These must be reflected in the informed consent and authorisation documents (see points 33.1.3 and 36.1.3).

(6) Unexpected harm and discomfort.

It is possible that participants may experience unforeseen harm or discomfort. When this occurs, said harm or discomfort shall not be concealed. A quick, efficient response to the situation shall be provided, with the participants receiving the corresponding level of care and the researchers or entity assuming any liability (for example, providing adequate professional care).

This commitment shall be reflected in the research protocol and in the informed consent document.

(7) Equal participation.

The invitation to participate in the study shall not overuse or marginalise any group. Concentrating research in a specific group of people or, in contrast, excluding any group of people with the same economic, social, ethnic, physical, psychological, gender conditions, etc. shall always be scientifically justified. This cannot be justified merely by a mere ease of observation or capture, which tends to be related to particularly vulnerable situations (for example, biomedical research involving prisoners or in countries or regions with few or no democratic guarantees). Furthermore, the inclusion of groups that despite suffering specific

difficulties in terms of access to participate in research projects, may be under-studied or overlooked, should be encouraged.

(8) Refrain from marginalising, stigmatising or any other form of injustice involving persons or groups.

In a world in which we still see tragic injustice, marginalisation and stigmatisation, research projects must be particularly sensitive to this matter, in order to refrain from feeding into these phenomena, and especially not generating them. Fair causes should be pursued and research should not contribute to the stigmatisation of or hate for persons or groups, in particular those deemed particularly vulnerable.

However, the CEI must be staunchly committed to scientific knowledge and ensure that politically correct ideology does not prevent it from doing its work.

(9) Non-participation in or withdrawal from a study shall not have a negative impact (objective or subjective) on the person.

Non-participation in or withdrawal from a study shall not have a negative impact on the care received by a person or their subjective perception of this situation.

Particular sensitivity and care for people deemed vulnerable or dependent is required, and strategies must be designed to ensure they do not feel discriminated against. For example, research conducted in a classroom, as part of which participating students undertake certain activities, must ensure that those who are not participating in the research are involved in alternative, equitable activities.

VI. Informed consent and informed authorisation.

Asking for permission is an ethical and, sometimes, a legal obligation. In this Guide, we distinguish between *informed consent* and *informed authorisation*. When a person or organisation's non-public data is collected, their informed consent or the informed consent of their legal representatives is required. For example, the informed consent of persons or organisations asked to fill in a questionnaire. When data is gathered at

an organisation or within its scope of responsibility, informed authorisation is required. For example, informed authorisation is required from the management team of the centre at which the questionnaire will be used or the town hall of the city in which passers-by will be asked questions.

(10) The informed consent of the individuals from whom data are collected, processed and stored.

(10.1) Importance of informed consent.

The horror of medical research on humans is not limited to the Nazi regime as part of the Third Reich. It was a phenomenon before this and has continued to be so afterwards, although under the Nazis it reached its brutal peak. In response to this, two main instruments were established as safeguards: Research Ethics Committees and informed consent.

The Nuremberg Code, drawn up by the International Military Tribunal in Nuremberg (1947), placed informed consent at the heart of research, with Article 1 of the Code indicating that:

> "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all discomfort and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his
>
> participation in the experiment.
>
> The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a

personal duty and responsibility which may not be delegated to another with impunity."

Informed consent is a process that, as its name indicates, consists of two phases: information and consent. The research protocol must provide an adequate description of this entire process and its content in addition to the informed consent and authorisation documents and information indicated in points 31 to 37.

The informed consent document consists of two parts: information and consent. These two parts must be considered a single document: the first is a testament to the explanation provided and the second that the information process has been undertaken correctly and that the person freely decides to participate in the study.

(10.2) Information.

(i) Oral and written information.

Whenever possible, information must be provided orally and in writing. Oral information must be conveyed in an understandable, personable, unhurried, accurate, comprehensive manner, using clear language adapted to the circumstances of the recipient.

This information must be reflected in a document, that also uses clear language that is understandable to the recipient, who will be provided with a copy. It will be explained to them and they will be given enough time to read it carefully and consult its content and their participation with whoever they believe necessary, should they deem it necessary.

When aimed at children or people with a serious intellectual disability, the use of pictograms is recommended.

As part of this process, the person invited to participate in the study may ask any questions they believe necessary, which shall be answered accordingly. If the research poses significant risks or discomfort, after the oral information is provided, sufficient time must be offered for the recipient to assess and consult, if they wish, their decision.

(ii) Only oral information.

The speed of some anonymous face-to-face research that does not pose any risks or discomfort, for example, an anonymous survey on the street, means that using only oral information is recommendable.

(iii) Only written information.

When the participation of individuals involves remote activities, such as filling in a questionnaire online or over the phone, and this activity does not pose any risks or discomfort to the person, the information process may make exclusive use of written information.

(10.3) Consent.

Once the person has been correctly informed, they shall provide their consent, which may be anonymous or nominal. Before looking at this matter, we first need to clarify the difference between *consent* and *legal consent*.

(i) *Consent* and *legal consent*.

In some linguistic contexts, it is necessary to distinguish between *consent* (a moral obligation) and *legal consent* (a legal duty). Not doing so could result in the ethical malpractice of not requesting consent from people that the law does not require consent from and, rather than merely being a legal duty, consent is a moral obligation.

The law reflects this matter by granting people from whom legal consent is not required the right to be heard, their opinion to be taken into account, their participation insofar as possible in decision-making processes, pursue their assent, etc.[10] However, these formulas do not equal consent, which

[10] This is established, for example, by Article 12 of the Convention on the Rights of the Child (1989); Article 9.3 of Law 41/2002, of 14 November, on the basic regulations of patient autonomy and the rights and duties in terms of clinical information and documentation; Article 9 of Organic Law 1/1996, of 15 January, on the legal protection of the minor, amending the Civil Code and the Civil

is a moral obligation. In terms of assent, the term means accepting what the other person has asserted or proposed as true or appropriate, which inevitably bestows upon certain groups the condition of dependency.

The warning and use of intimacy and freedom is a learning and biological development process. The law tries to adapt to this biopsychosocial process establishing four age bands that must be taken into consideration: aged over twelve, the child must be heard and their opinion taken into account[11]; aged over fourteen, they may give consent for the processing of their personal data [12]; aged over sixteen, they may be granted emancipation and their consent shall be required for any procedure affecting their health[13] and aged over eighteen, they shall be considered of

Procedure Law. Article 92.2 of the Civil Code and Articles 770.4 and 777.5 of the Civil Procedure Law.

[11] Article 211-6.2 of the Civil Code of Catalonia asserts: "Minors, based on their age and natural capacity and, in any case, when they turn twelve, have the right to be informed and heard before any decision is made directly affecting their personal circumstances or property". The same goes for Spanish legislation. Article 9 of the Law on the Protection of Minors indicates: "1. Minors have the right to be heard without discrimination on account of their age, disability or any other circumstance, both in the family environment or as part of any administrative, legal or mediation procedure they are involved in and that results in a decision that affects their personal, family or social environment, duly taking into consideration their opinions, based on their age and maturity. To this end, minors shall receive the information that allows them to exercise this right in understandable language, in an accessible format and adapted to their circumstances. […] / 2. It shall be guaranteed that minors, when they are mature enough, will be able to exercise this right on their own or through the person appointed to represent them. Their maturity shall be assessed by specialist staff, considering both the minor's development and their ability to understand and assess the specific matter in hand on a case by case basis. In any case, it shall be considered that they are mature enough when they turn twelve. / To ensure that minors can exercise this right by themselves, they will be assisted, when necessary, by an interpreter. Minors may express their opinion verbally or using non-verbal forms of communication. / However, when this is not possible or is not in the interest of the minor, their opinion may be conveyed by their legal representative, provided that their interests do not conflict, or by other persons who, given their profession or special relationship or trust with the minor, can convey their opinion objectively." In addition to Article 92.1 of the Civil Code ("The judge, when adopting a resolution in relation to the custody, care and education of minors, shall ensure compliance with their right to be heard"); Article 770.4 of the Civil Procedure Law (as part of petitions for separation and when deemed necessary "minors or disabled children with proper judgement shall be heard, as shall all children aged over twelve") and Article 777.5 of the same law.

[12] Article 7 of the LOPDGDD indicates: "1. The processing of a minor's personal data may only be based on their consent when they are aged fourteen or over. Exceptions shall be made when the law requires the presence of the parents or guardians to enter into the legal relationship or undertake the legal act in which context consent for processing is sought. 2. The processing of data pertaining to minors aged under fourteen, based on consent, shall only be considered lawful when the consent of the parent or guardian is also obtained, to the extent established by the parents or guardians."

[13] Articles 211-7 to 211-11 of the Catalan Civil Code on the emancipation of minors. Article 212-2.1 of the Civil Code of Catalonia asserts: "Persons aged over sixteen and minors with sufficient intellectual and emotional maturity to understand the scope of the procedure affecting their health may offer consent on their own behalf, unless the health legislation establishes otherwise". And Article 7.2.d of

legal age and, therefore, fully capable of exercising all their rights, pursuant to any limitations that may be established in a legal ruling on support or protection measures.

(ii) Anonymous consent.

In studies where anonymous data are obtained, consent is provided at the same time as the activity is carried out, for example, when responding to an anonymous questionnaire; consent is refused by not performing the activity, for example, not responding to the questionnaire. No nominal authorisation is required, as this would entail breaching the person's anonymity. The informational part is required.

(iii) Nominal consent.

This Guide refers to nominal consent in the sense that the person provides their consent by identifying themselves and signing the second part of the consent document.

In studies involving questionnaires or other over-the-phone or online activities in which the person's identification is required, nominal consent may be provided by email in which consent is indicated, a voice recording, etc.

(11) Informed authorisation of organisations at which data is collected.

When gathering data at an organisation or within its scope of responsibility, informed authorisation must be obtained from this organisation. For example, surveys or questionnaires carried out in a home for the elderly shall have the authorisation of the centre's management; or surveys or questionnaires carried out

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Catalan Law 21/2000, of 29 December, on information rights concerning health and patient autonomy and clinical documentation: "In the case of minors, if they are not considered to be intellectually or emotionally competent in terms of understanding the scope of the procedure affecting their health, consent shall be provided by the representative of the minor, having heard their opinion, when the minor is aged over twelve. In other cases, and particularly in terms of emancipated minors and adolescents aged over sixteen, consent must be offered in person."

in the street shall have the authorisation of the corresponding local council (even when there is no legal regulation that requires it, it is an ethical rule that those responsible for public spaces should know and authorise the studies carried out in them) (see Guidelines 35, 36 and 37).

The informed authorisation document consists of two parts: information and consent. These two parts must be considered a single document: the first is a testament to the information provided and the second that this process has been undertaken correctly and that the organisation authorises the research being conducted.

(12) Passive or tacit consent is not acceptable.

Passive or tacit consent is understood as the consent obtained by the person's passivity; in other words, not by the actions of the affected party (for example, responding to an anonymous survey or signing the informed consent document) but rather their lack of action (for example, when parents are asked whether they do not want their child to participate in a research project at school, they must say so, as otherwise it will be considered that they accept).

Passive or tacit consent is ethically and legally incorrect. The GDPR states that informed consent is a "freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her" (Article 4.11). So to eliminate any ambiguity, Preamble 32 insists on this matter and indicates that silence or inaction shall not be considered consent[14].

[14] "Consent should be given by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of the data subject's agreement to the processing of personal data relating to him or her, such as by a written statement, including by electronic means, or an oral statement. This could include ticking a box when visiting an internet website, choosing technical settings for information society services or another statement or conduct which clearly indicates in this context the data subject's acceptance of the proposed processing of his or her personal data. Silence, pre-ticked boxes or inactivity should not therefore constitute consent. Consent should cover all processing activities carried out for the same purpose or purposes. When the processing has multiple purposes, consent should be given for all of them. If the data subject's consent is to be given following a request by electronic means, the request must be clear, concise and not unnecessarily disruptive to the use of the service for which it is provided."

Furthermore, Article 6.1 of the LOPDGDD indicates:

> "the subject's consent shall be understood as an act establishing their freely given, specific, informed and unambiguous agreement as part of which they accept, by means of a statement or clear, affirmative action, the processing of their personal data" and in the Preamble, for the purposes of clarity, it is indicated that this affirmative action on the part of the subject excludes "what is known as tacit consent".

(13) Possible factors of power or dependency, conflict of interests or vulnerability in the process of inviting subjects to participate in the study.

As part of the process for inviting subjects to participate in the study, any factor that may have an undue influence on consent must be avoided; for example, the formal or informal power demonstrated by the researcher (whether through their oral or body languages), dependent relationships, conflict of interests, vulnerability of the person invited to participate, etc.[15]

The research protocol must (i) analyse the possible factors of power or dependency, conflict of interests or vulnerability, as applicable, and (ii) list the actions to be performed to avoid or neutralise them.

In terms of the dependent relationships between people invited to participate in the research and the researcher (on account of their status as their therapist, professor, superior, etc.), ideally, no professional should participate in research with people with whom he or she has a professional relationship, unless it is possible to guarantee *(i)* that during the process of inviting participants, procedures are established that cancel out any undue influence and *(ii)* the anonymity of the participants before the researcher with whom they maintain a professional relationship.

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[15] The research on obedience to authority begun by philosopher Hannah Arendt (*Eichmann in Jerusalem: a Report on the Banality of Evil* (1963)) and continued by social psychologist Stanley Milgram ("Behavioral Study of Obedience" (1963) and *Obedience to authority. An experimental view* (1974)) is both enlightening and tragic.

(14) Incognito (or naturalist) observation.

As a general rule, incognito (or naturalist) observations should be avoided, as they represent an assault on the privacy of individuals and are contrary to the principles of respect, consent, honesty and transparency.

However, in certain studies in the fields of psychology, psychiatric, anthropology, etc. incognito (or naturalist) observations may be required to achieve the objectives pursued or because it is not possible to inform the individuals being observed. In these situations, exceptions may be made provided that these five conditions are satisfied:

(i) The incognito (or naturalist) observation is strictly necessary from a methodological perspective (there is no other known way of achieving the same or similar results).

(ii) The research will generate relevant scientific knowledge about the group subject to study.

(iii) Only anonymous data can be gathered as part of the observation work, never personal data that can be used to identify a person (for example, when taking images, the face and other bodily parts that can be used to identify the person will be blurred).

(iv) The observation is not intrusive and does not and will not cause any reasonable harm, discomfort, embarrassment or anger in the persons observed. Particular care must be taken with observation procedures and anonymity.

(v) The observation is conducted in public spaces in which knowing or imagining you are being observed by unknown people does not breach the right to privacy. When the observation is conducted in public or private spaces in which access is controlled (museums, libraries, civil centres, schools, swimming pools, etc.), the informed consent of management will be required.

(15) Incognito sociological or journalistic research.

On occasion, sociological or journalistic research requires data being obtained from people or organisations without their knowledge or consent. For example, research about people or organisations with political or economic motives or infiltration of an extremist movement.

Unlike the incognito observation indicated above, this type of research cannot be planned in detail in a scientific research protocol, but it may obtain and even publish personal data.

For this type of research project, the CEI shall assess the unmistakable public or scientific interest of the data that the researcher is looking to obtain and ensure that they do not surpass the limits of respect for the dignity of people.

(16) Deceptive methodology and hiding information from participants.

As a rule, deceit or hiding significant data in the information process from people invited to participate in research is not acceptable, as this is against the principles of respect and honesty and the rights of freedom, privacy and dignity of the person.

However, in certain studies in the fields of psychology, psychiatric, anthropology, etc. deceit and hiding information from participants may be required to achieve the objectives pursued. In these situations, exceptions may be made provided that these nine conditions are satisfied:

(i) The deceit or hiding of information is strictly necessary from a methodological perspective (there is no other known way of achieving the same or similar results).

(ii) The research will generate relevant scientific knowledge about the group subject to study.

(iii) Provided that it does not interfere with the results, the participants shall be informed that there are certain aspects of the research that cannot be revealed until it is over.

(iv) Deceit or hiding of information shall not cause any harm to the participants during their involvement in the study.

(v) Once the research is over, or before whenever this is possible and will not harm, discomfit or anger the person participating in the research, they will be informed of the truth or whatever information was withheld.

(vi) It shall be ensured that once informed, participants can exercise their right for all the data obtained from them to be removed. Therefore, in this type of research, data may not be anonymous until it is finalised.

(vii) If people deemed particularly vulnerable participate in this research, it cannot be conducted with comparable effectiveness to those not in this situation.

(viii) When the deceit or hiding of information affects minors or adults receiving legal support measures, the guardians or carers must be informed of the truth or be provided with all the information.

(ix) The study shall take particular care in terms of the individuals deceived or from whom information is withheld.

(17) Very long-term research.

For research in which people are required to participate for very long periods, the informed consent of those participating in the research and who are affected by any changes[16].

[16] Point 3.3.*i* in the Best Clinical Practice (BPC) guidelines for trials with pharmaceuticals (WHO-1995). Rule 4.8.2 and 4.8.11 of the Best Clinical Practice Guideline CPMP/ICH/95. Comment about point 4 ("Renewal of consent") of the International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002). Article 25.5 of Law 14/2007 on biomedical research deems that informing the patient or their legal representative would be sufficient. It states: "Any relevant information about participation in the research must be communicated to the participants and, if applicable, their representatives, as quickly as possible."

(18) Online surveys and questionnaires.

Online forms may be anonymous (data gathered is anonymous) or not (data gathered is personal).

(18.1) Anonymous.

In relation to anonymous questionnaires, two observations are worth mention: (i) before starting to fill in the form, information shall be indicated about the research project (see point 33.1 on contents of the informational part) and (ii) consent is provided at the time of answering the survey or questionnaire (anonymous consent) and the refusal to provide consent, by not filling in the form, meaning that there shall be no nominal consent.

(18.2) Non-anonymous (personal data).

In relation to non-anonymous questionnaires, two observations are worth mention: (i) before starting to fill in the survey or questionnaire, information shall be indicated about the research project (see point 34.1 on contents of the informational part) and (ii) the person must provide their nominal consent (see point 34.2 on the contents of the consent part).

(19) Anonymous surveys or questionnaires carried out in the street.

Anonymous surveys or questionnaires conducted in the street shall satisfy the following four conditions:

(i) The researcher shall identify themselves in a visible location using their name, photo, function and logo of the entity on whose behalf the research is being conducted.

(ii) The researcher shall identify themselves politely, explaining their work and invite the person or persons to participate, without insisting or applying pressure.

(iii) If possible, they shall provide the potential participants with a leaflet containing information about the research project. Sometimes, a desk may be set up at appropriate locations with leaflets, posters and material illustrating and explaining the research project.

(iv) Authorisation shall be requested from the local town hall. If the survey or questionnaire is conducted while an event is being held, authorisation shall be requested from the organisers (as indicated in point 11).

VII. Intimacy: extimacy and data protection.

(20) Respect for the *extimacy* of the person (their body, their associates, their spaces and their things).

Respect for a person's intimacy is not limited to the processes in which it is obtained, processed and stored, but rather, the way in which their *extimacy* (their body, their associates, their spaces and their things) is treated. If the research methodology requires very personal treatment of the participant (for example, touching them, entering their home, asking intimate questions, etc.), the protocol must establish guidelines, instructions and commitments in terms of proper treatment to respect this expression of intimacy.

(21) Data minimisation (whether anonymous or personal data).

As part of research in which anonymous or personal data is gathered, these must be fair and necessary in achieving the proposed objectives. This principle, known as the *data minimisation principle*, is an ethical, legal and scientific requirement. Ethical, because it is a sign of respect that the authorised intrusion in a person's life is kept to a minimum (respect for their intimacy) and they are not asked to conduct useless activities. Legal because that is what the law stipulates[17]. Scientific, because not multiplying the number of data, hypotheses, theories, etc. unnecessarily is a basic epistemological principle.

(22) Collection and processing of anonymous data.

Two clarifications are necessary regarding data processing in general:

a) **Regarding the meaning of the concept *data processing*.** The GDPR defines processing as "any operation or set of operations which is performed upon personal data or sets of personal data, whether or not by automatic

[17] Article 5(1) of the GDPR defines the principle of data minimisation as follows: "Personal data shall be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation')."

means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction" (Art. 4).

However, in order to bring the language as close as possible to the use and understanding of researchers, and except for textual quotations or explicit reference to legal regulations, the expressions *data collection, processing and safekeeping* will be used here where *processing* includes everything that the GDPR states except collection and safekeeping.

b) **Regarding the concepts of *personal data*, *personal information*, *anonymous information*, *personal data* and *anonymous data*.** The GDPR and the Organic Law on Data Protection and the Guarantee of Digital Rights, establish a difference between *personal data* and *anonymous information*. Personal data is any information about an identified or identifiable natural person[18]. Therefore, information is anonymous and becomes personal data when it is possible to identify the person or persons referred to, as a result, the duty of protection does not extend to anonymous information.

The difference between personal data and anonymous information may cause confusion in some scientific areas, where *data* can also refer to anonymous data, for example, a statistic data, and *information* can also refer to personal data, for example when a health professional informs a patient regarding their disease. In order to avoid confusion, we will use the terms *personal data and anonymous data* and reserve *information* to inform or give news of something.

The obligations outlined in the GDPR and the LOPDGDD do not affect research projects that obtain and process anonymous data[19]. However, there are also duties

[18] Preamble number 26 and Article 4.1. of the GDPR.

[19] Preamble number 26 of the GDPR indicates the following: "The principles of data protection should therefore not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner

regarding the data in this research, and the following issues shall be specified in the research protocol:

(i) Security measures when collecting anonymous data.

If data is obtained online, an explanation about the degree of security offered by these instruments must be provided. Any computer platform or tool that operates online must ensure the security of the process for collecting data, including anonymous surveys and questionnaires, as the IP address can be identified. Using platforms and tools run by companies recommended by universities or certified companies in the National Security Framework (ENS) is recommended[20].

(i) Name of the organisation responsible for collecting, processing and storing the anonymous data and how to contact it.

If the research is conducted at an organisation, the name of the organisation responsible for collecting, processing and storing the anonymous data and how to contact it.

(4) Name of the researcher specifically responsible for collecting, processing and storing anonymous data and how to contact them.

If the research is conducted within an organisation, the telephone number, email, etc. should be institutional.

(23) Collection, processing, storage and destruction of personal data.

The research protocol must contain detailed information about the aspects indicated below:

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that the data subject is not or no longer identifiable. This Regulation does not therefore concern the processing of such anonymous information, including for statistical or research purposes."

[20] The National Cryptological Centre (CCN) offers a list of companies providing outsourced services and that are certified by the National Security Framework (ENS). It can be consulted at https://www.ccn.cni.es/index.php/es/esquema-nacional-de-seguridad-ens/empresas-certificadas

(i) Security measures when collecting personal data.

See content of point 22(i).

(ii) Security measures when processing and storing personal data.

An explanation shall be provided of how and where personal data will be stored (informed consent documents, answers to questionnaires, recordings, correspondence table, etc.), the procedures and the security measures that shall be employed to ensure their protection, who will have access to them, the processing procedures and instruments (electronic systems, if databases shared online with other centres or researchers are being used, whether data will be transferred outside the European Union etc.), etc.

(iii) Anonymisation, pseudonymisation and self-chosen pseudonymisation, as applicable.

The research protocol shall explain whether the data to be gathered are anonymous or personal. When personal data are gathered, an explanation shall be provided as to whether they will be anonymised, pseudonymised or subject to self-chosen pseudonymisation, or whether none of these highly recommendable procedures will be performed.

Anonymisation is the procedure via which personal data are converted into anonymous data. When anonymisation takes place, it is no longer possible to connect data to a specific person and, therefore, the persons are no longer identifiable using reasonable procedures and efforts[21].

[21] Preamble 26 of the GDPR, as regards reasonable procedures and efforts, indicates the following: "To ascertain whether means are reasonably likely to be used to identify the natural person, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration the available technology at the time of the processing and technological developments."

Pseudonymisation is the process through which personal data cannot be attributed to a specific person without using additional information[22]. The most common procedure involves applying a code to each person in a table of correspondence[23] in such a way that it is only possible to associate them with a specific person when in possession of said table of correspondence[24]. In these cases, the pseudonymisation procedure must be explained, as must the measures established to guarantee the protection of the correspondence table, who will have access to the table and when it will be destroyed.

In some longitudinal research, pseudonymisation involves the participants choosing the code or pseudonym that only they know. As part of this procedure, the person is asked to choose a password that only they are aware of for the tasks entrusted to them (for example, answering a survey or questionnaire). This code allows researchers to connect the data gathered to a person, who remains anonymous to them; and the participant in the study is able to exercise their rights of access, rectification, erasure, limitation and opposition. We will refer to this procedure as *self-chosen pseudonymisation*[25]. In these cases, the self-chosen pseudonymisation process must be explained, the measures established to ensure that nobody but the participant can connect them to their code

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[22] According to Article 4 of the GDPR, pseudonymisation means "the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person."

[23] There is also reference to an *encoding table* or *list*, or a *decoding table* or *list*. In this Guide we will use the concept of a *correlation table*.

[24] Foe a detailed description of pseudonymisation and the different pseudonymisation techniques, consult the European Union Agency For Network and Information Security (2018). *Recommendations on shaping technology according to GDPR provisions. An overview on data pseudonymisation*

[25] The European Union Agency For Network and Information Security (2018: 1213) indicates that self-chosen pseudonyms should not be confused with pseudonymisation under the GDPR, as using pseudonyms, it is not possible to identify specific individuals by correlating them with relevant data. However, it refers to the pseudonyms and data on social media, which in some cases can be used to identify people. Therefore, in this Guide we have chosen to use the term self-chosen pseudonymisation for the purpose in which the person themselves psuedonymises their identity under the terms explained above.

or pseudonym and decide when anonymisation will occur; in other words, when it will be impossible to connect the code or pseudonym to the data.

Pseudonymisation makes it possible to (re)identify the person, while anonymisation does not. The processing and storing of pseudonymised data has to comply with the data protection laws in force, whereas the processing and storing of anonymised data (information) does not. Pseudonymised data are considered personal data until the table of correspondence that enables identification is deleted.

(iv) Name of the organisation responsible for collecting, processing and storing personal data and contact for the exercise of the corresponding rights.

If the research is conducted at an organisation, the name of the organisation responsible for collecting, processing and storing the data and the method for contacting the data protection officer [26] at the organisation to exercise all the corresponding rights are required.

In relation to research conducted at an organisation, for example, a university, it is this entity that is responsible for collecting, processing and storing personal data, meaning that the procedures established by this organisation must be followed[27].

[26] The data controller is the natural or legal person, public authority, service or other organisation that, in the performance of their activities, processes personal data. The data processor is the natural or legal person, service or other organisation that, in the performance of their activities, processes data for which the data controller is responsible. The data protection officer (DPO) is a professional with specialist knowledge of data protection regulations and practices, whose role it is to help the data controller or processor. This may be an internal or external individual and must be able to perform their duties independently (Articles 4.7, 4.8 and 37 of the GDPR).

[27] For the University of Girona, consult https://www.udg.edu/ca/protecciodedades/

(v) Name of the specific researcher responsible for collecting, processing and storing personal data and contact for the exercise of the corresponding rights.

(vi) Where to obtain more information on the processing and storage of personal data.

When collecting personal data, a wide range of information may have to be provided to participants in relation to the processing and storage of their data[28]; so ideally, they shall be provided with the most relevant information first and an easy way to access the rest of the information[29], which tends to be the same for all or almost all data processing and storage conducted by an organisation[30].

(vii) Time limits for personal data storage and destruction process.

The time limits for storing files containing personal data (including informed consent forms signed by the participants and the table of correspondence, as applicable) shall be determined, as shall the fact that the files will be destroyed by applying procedures that satisfy the corresponding safety measures[31].

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[28] Article 13 of the GDPR sets out the information that must be provided when personal data are obtained from the subject.

[29] This is also set out under Article 11 of the LOPDGDD. This Article indicates that the basic information must contain, at least (a) the identity of the data controller and their representative, as applicable. (b) The purpose of treatment and (c) the ability to exercise the corresponding rights established in Articles 15 to 22 of the GDPR.

[30] For the University of Girona, consult https://www.udg.edu/ca/protecciodedades/.

[31] The GDPR indicates that personal data must be conserved for a limited time period, but does not stipulate specific time periods, rather it refers to proportionality as the limitation principal, in other words, the storage times must be the periods strictly necessary to satisfy the purpose for which the personal data was gathered.

The GDPR and LOPDGDD establish exceptions to the rule and allow for time limits for personal data storage to be extended when the data may be of public, historic, scientific, statistical or informational interest. In any case, whenever possible, this data should be anonymised to prevent the identification of the persons it belongs to.

(24) Limitation of the purpose of personal data and their use for purposes other than those for which they were obtained.

(i) Limitation of the purpose.

In principle, the personal data shall only be used for the purposes for which they were obtained and for which informed consent was obtained from the participant. If they are used for other purposes and have not been anonymised, informed consent shall be requested from the participant again.

As it is not always possible to fully determine the purpose of data processing as part of research processes, preamble number 33 of the GDPR indicates: "It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose." Furthermore, the Preamble of the LOPDGDD, when ruling out the possibility of tacit consent, indicates that when "consent from the subject is required for multiple purposes, it shall be specifically and unmistakably indicated that they grant their consent for all these purposes".

(ii) Use for purposes other than those for which they were obtained.

However, the law allows for exceptions to the principle of limitation of the purpose. Article 5.1.b of the GDPR indicates:

> "Personal data shall be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation')."

And Article 89.1 (Safeguards and derogations relating to processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes) asserts:

> "Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner."

Likewise, Article 6.4 of the GDPR indicates:

> "4. Where the processing for a purpose other than that for which the personal data have been collected is not based on the data subject's consent or on a Union or Member State law which constitutes a necessary and proportionate measure in a democratic society to safeguard the objectives referred to in Article 23(1), the controller shall, in order to ascertain whether processing for another purpose is compatible with the purpose for which the personal data are initially collected, take into account, inter alia:
>
> a) any link between the purposes for which the personal data have been collected and the purposes of the intended further processing;
>
> b) the context in which the personal data have been collected, in particular regarding the relationship between data subjects and the controller;
>
> c) the nature of the personal data, in particular whether special categories of personal data are processed, pursuant to Article 9, or whether personal data related to criminal convictions and offences are processed, pursuant to Article 10;
>
> d) the possible consequences of the intended further processing for data subjects;

e) the existence of appropriate safeguards, which may include encryption or pseudonymisation.

As regards the use of university student email addresses, for example, for research purposes, at least these two considerations shall be satisfied: the first, that unauthorised communications are a nuisance to recipients and in our connected society, these must be reduced; the second, that the contractual relationship established between the student and institution is a teaching relationship, therefore, unless indicated otherwise, it shall be considered that this is the purpose of the email address.

(25) Data Protection Impact Assessment (DPIA).

Article 35 of the GDPR states that it shall be the duty of data controllers to conduct a data protection impact assessment (DPIA) when it is likely that the processing of data entails a high risk to the rights and freedoms of the person[32]. The GDPR does not provide a description of "high risk", merely listing three cases in which the DPIA is mandatory and refers to what is established by the supervisory authorities. Therefore, it is necessary to resort to the indications of the Article 29 Working Party (Art. 29 WP), predecessor of the current European Data Protection Committee (EDPC)[33], and the guidelines of data protection agencies and authorities[34]. These indications set out nine criteria or high-risk

[32] This obligation is also established by Article 27 of *Directive (EU) 2016/680 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 by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data* (https://www.boe.es/doue/2016/119/L00089-00131.pdf.). It states that an impact assessment in terms of privacy shall be conducted whenever it is likely that processing "result in a high risk to the rights and freedoms of natural persons".

[33] Article 29 Data Protection Working Party (2017). *Guidelines on the data Protection Impact Assessment (DPIA) and to determine whether processing "is likely to result in a high risk" for the purposes of Regulation (EU) 2016/679*. https://www.aepd.es/sites/default/files/2019-09/wp248rev01-es.pdf.

[34] In our case, we have received guidance from the Catalan Data Protection Authority (APDCAT): *Guia pràctica. Avaluació d'impacte relativa a la protecció de dades* taken from (https://apdcat.gencat.cat/web/.content/03-documentacio/Reglament_general_de_proteccio_de_dades/documents/Guia-Practica-avaluacio-impacte-proteccio-de-dades-2019.pdf) and *Llista de tipus de tractaments de dades que requereixen avaluació d'impacte relativa a la protección de dades*, also taken from APDCAT (https://apdcat.gencat.cat/web/.content/02-drets_i_obligacions/obligacions/documents/Lista-DPIA-CAT.pdf).

characteristics; when two of these occur, a DPIA is required and, in some cases, the data controller may determine that processing incurring in one of these criteria or characteristics requires a DPIA. The more criteria or characteristics involved in the processing, the higher the risk for the rights and freedoms of the subjects.

These nine criteria and characteristics are:

(i) Processing that involves the creation of profiles, assessments or predictions, in particular when gathering personal data in relation to various aspects of the person ("aspects relating to performance at work, economic situation, health, personal interests or preferences, reliability or behaviour, status and movements of the subject"). For example, a biotechnology company that offers genetic tests to assess and predict the risk of suffering illnesses, a company that draws up behavioural profiles based on web browsing history.

(ii) Processing that involves automated decision making or that contribute in large part to these decisions being taken, including any type of decision that prevents a subject from exercising a right or accessing a good or service or being party to a contract. For example, automated processing that may result in exclusion or discrimination.

(iii) Processing that involved the systematic and exhaustive observation, monitoring, supervision, geolocalisation or control of the subject, including the collection of personal data and metadata online, via applications or in areas that are publicly accessible. Processing of unique identifiers that make it possible to identify the users of information society services, such as online services, interactive television, mobile applications, etc.

(iv) Processing that involves sensitive or very personal data. This includes the special personal data categories indicated in Article 9 of the GDPR, for example: racial or ethnic origin, political or philosophical opinions, belonging to a trade union, genetic data, biometric data processed with a view to exclusively identifying a person, health-related data, data regarding sexual orientation or sex life, data on criminal penalties or offences, data that increases the risk to the rights and freedoms of people (such as

electronic communication data, location data and financial data, personal documents, email, journals, notes by readers of e-books and personal information included in applications recording vital activities, etc.).

(v) Large-scale processing of personal data. To determine whether processing is being performed on a large scale, consideration must be given to the following factors: the number of subjects (in absolute or relative terms), the volume or variety of personal data, the duration of the personal data processing activity, the geographic scope of processing activities.

(vi) Processing that entails the association, combination or connection of personal database records from two or more processing activities with different purposes or controllers.

(vii) Processing of personal data in relation to persons deemed vulnerable: children, students, adults with mental illnesses, people with disabilities, the elderly, patients, asylum seekers, victims of gender violence, in addition to their descendants and persons under their custody, and any other situation in which it is detected that there is an imbalance of power between the subject and the controller.

(viii) Processing that involves the use of new technologies or an innovative use of consolidated technologies, including the use of technologies to a new scale, with a new goal or combined with others, in such a way that this entails new ways of gathering and using personal data with a risk to the rights and freedoms of individuals. For example, combining the use of fingerprints and facial recognition.

(ix) Personal data processing that prevents subjects from exercising their rights, using a service or enforcing a contract. For example, the processing of personal data that has been gathered by one or more controller and processed by another, and to which any of the information exceptions offered to the subjects as per Article 14.5 (b, c, d) of the GDPR applies.

If the processing of personal data is considered high risk, the researcher shall foresee and commit to applying the necessary safety measures to reduce the level of risk to medium or low. To this end, it will not be enough to guarantee the

security of processing via secure and certified platforms, rather it will be necessary to reduce the level of risk applying other measures, for example, restricting access to certain types of personal data, anonymising data as quickly as possible, preventing the processing of certain types of particularly sensitive personal data, etc.

The Catalan Data Protection Authority offers a tool that helps to do the DPIA and that can be downloaded from its website, in addition to a Manual and Practical Guide (https://apdcat.gencat.cat/ca/drets_i_obligacions/responsables/obligacions/avaluacio-impacte-relativa-proteccio-dades/).

VIII. Participation of persons deemed particularly vulnerable.

(26) Participation of persons without full use of reason or maturity.

Research can only be undertaken involving persons who do not have the cognitive ability to provide their informed consent (children, people with serious intellectual disabilities, people with an acute mental illnesses, people at an advanced state of a neurodegenerative disease, etc.), when the following five conditions are met[35]:

(i) The research cannot be conducted with a level of effectiveness comparable to other people who have full use of reason.

(ii) The research is expected to generate short, medium or long-term benefits for the participants or a benefit for the group they represent.

[35] The legal texts that address these conditions are, including but not limited to: Regulation (EU) 536/2014 of the European Parliament and of the Council, of 16 April 2014 , on clinical trials on medicinal products for human use, and Royal Decree 1090/2015, of 4 December, regulating clinical trials on medicinal products, Research Ethics Committees with medicinal products and the Spanish Clinical Trial Register.

(iii) The research does not pose any risks or discomfort to the participants[36].

This third condition may not apply to adults with a recent cognitive disability who had previously agreed to participate in some form of research in the form of an advanced directives document. In these cases, the criteria of proportionality and prudence shall apply.

(iv) Informed legal consent is obtained from the progenitors or legal representative, as applicable.

(v) Consent is obtained from the person invited to participate or they do not refuse to participate in the study.

Based on the provisions of point 10.3i on the differentiation between consent and legal consent, in situations in which legal consent is required from a representative and provided that it is possible:

— Information will also be provided to the person invited to participate, in language that is understandable to them based on their condition.

— If they do not wish to participate, their wishes shall be respected.

— If they do with to participate, they will be asked to sign the consent document[37].

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[36] In the case of *compassionate processing or use*, the relationship between the expected benefits, the risks and discomfort of participating in the study must be significantly higher than the standard processing required by the person.

[37] Of the legal texts that concur with this ethical guideline, the following are worth particular mention: Article 12 of the Convention on the Rights of the Child (1989) indicates that the child has the right to express their opinion in all matters that affect them and for their opinion to be taken into consideration based on their age and maturity; and Article 12 of the Convention on the Rights of Persons with Disabilities (2006) insists on the need to respect the wishes and preferences of persons with a disability.

(27) Participation of persons deemed to be culturally vulnerable: cultural mediator.

As part of research in which persons deemed to be culturally vulnerable participate (for example, they are illiterate, or do not speak the same language as the researchers, or because their cultural background is very different to that of the researchers), the presence of an unbiased cultural mediator from outside the research team is required throughout the informed consent process and, if necessary, throughout the entire research process.

(28) Assistance provided to the CEI by experts or persons with the same profile as the participants.

When the CEI appraises research projects in which minors, adults without full use of reason or persons deemed particularly vulnerable participate and there are factors that are unknown to members of the CEI that may be relevant, at least one expert in the group subject to study shall participate in the appraisal, or their advice must have been sought[38].

During the ethical appraisal of research projects, it is a good idea for the analysis and assessment of certain variables, for the appraisers to perform the exercise of putting themselves in the participant's position. However, sometimes it is difficult

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The first standard that established respect for the desires of children and persons with an intellectual disability to participate in clinical research or not, was Article 12.5 of Royal Decree 561/1993, of 16 April, which established the requirements for conducting clinical trials with medicinal products ("When the conditions of the subject so permit, and in any case, when the minor is aged twelve or over, they shall also be required to express their consent (appendix 6, section 2) to participate in the trial, after having been provided with all the corresponding information adapted to their level of understanding"). At present, and in terms of clinical trials conducted involving minors, this requirement appears in Article 5.3 of Royal Decree 1090/2015, of 4 December, regulating clinical trials on medicinal products, Research Ethics Committees with medicinal products and the Spanish Clinical Trial Register, which states that: "When the conditions of the subject so permit, and in any case, when the minor is aged twelve or over, they shall also be required to express their consent."

[38] In terms of clinical trials involving minors, this requirement appears in Article 5.2 of Royal Decree 1090/2015, of 4 December, regulating clinical trials on medicinal products, Research Ethics Committees with medicinal products and the Spanish Clinical Trial Register. It states: "The members of the CEIm responsible for appraising part II of the appraisal report of a clinical trial involving minors shall include experts in paediatrics or have received advice on clinical, ethical and psychosocial matters in the field of paediatrics."

to do this, as the other person's reality is often far removed from our own. In these situations, it is advisable that persons with the same profile as the participants are involved or provide advice.

IX. Financial aspects.

(29) The research protocol, or a separate report, shall provide clear, accurate information about the financial aspects.

The research protocol or a separate report shall provide information on:

(i) Sources of funding.

(ii) Extraordinary compensation to be received by researchers (not ordinary compensation), if any.

(iii) Compensation or gifts, if any, to be received by the participants.

(iv) The financial impact that the results of the research may have.

Some research may be of significant financial interest and the CEI must be aware of and assess this aspect with a view to ensuring transparency and honesty.

If the researchers have an ordinary contractual relationship with the organisation in the framework of which the study is being conducted (for example, a university), the research protocol or financial report shall indicate that the research forms part of their employment responsibilities and, therefore, their ordinary financial remuneration.

The sources of funding shall also appear in the informed consent and authorisation document (see points 33, 34, 36 and 37).

(30) The relationship between financial benefits, economic compensation, risks and discomforts and the terms of participation.

In research that generates or may generate economic benefits in the short or medium term, the CEI should assess the relationship between these variables:

(i) Economic benefits generated or likely to be generated by the research.

(ii) Extraordinary compensation received or to be received by researchers, if any.

(iii) The risks and discomfort to which participants may be subjected.

(iv) The reasons and terms on which people are invited to participate (motives, volunteering, possible financial compensation, reference to the economic impact the research results may have, etc.).

The invitation to participate voluntarily in a research project, appealing to the social benefits that it may offer, shall not hide or minimise the financial benefits, if any, that the research will produce or is producing for the organisations or the researchers.

(31) Financial or other compensation to participants.

No research project shall require that the participant bear any costs, whether directly or indirectly. When they do bear such costs, they shall be reimbursed for them. This aspect is particularly important when the research involves risks or discomfort. Furthermore, and on first impression, remuneration should not entail an incentive to participate in a research project, as this may result in the overuse of impoverished groups.

Sometimes, it is not easy to distinguish between financial or other compensation that offsets the discomfort caused by the research and an incentive that encourages participation. To this end, when remuneration is offered, it shall be appraised by the CEI looking at the possible costs, risks and discomfort and the vulnerability of those invited to participate, to avoid their circumstances from being exploited.

INFORMED CONSENT DOCUMENT (PARTICIPANTS AND LEGAL REPRESENTATIVES). ASPECTS TO BE ASSESSED.

As indicated in point 11, when gathering the private data of a person or organisation, their informed consent is required, which shall include and consider the matters indicated below:

(32) Language and treatment.

(i) The information and consent shall be drafted in the official languages of the location in which the data is gathered. If the persons involved do not understand these languages, a cultural mediator (see point 27) shall be present, or the information and consent shall be drafted in their language.

(ii) The information and consent shall be written in a clear language that is easily understandable to the persons it is aimed at and, therefore, adapted to their conditions and circumstances. The use of acronyms and technical language shall be avoided insofar as possible.

If the participants are unable to read, do not understand the languages in which the informed consent document is written or experience difficulties doing so, an adequate response to this situation must be given; for example, preparing it in easy-to-understand language, in a language that is understandable to them, using pictograms, etc. The document layout shall also facilitate its reading.

(iii) The language shall be respectful and formal.

(33) When gathering anonymous data

(33.1) Contents of the informational part.

Information shall be provided, adapting it truthfully, honestly and reasonably to the characteristics of each research process and invitation to participate in the study (face to face, over the phone, online, etc.), about the following:

(33.1.1) General information.

(i) Name of the research project.

(ii) Invitation for the person or organisation to participate in the research.

(iii) Name of the principal researchers, email address and contact phone number, which shall be institutional, not private.

(iv) Organisation at which the research project is being conducted, as applicable.

(v) Sources of funding, as applicable.

(vi) Aims and hypotheses of the project and a brief explanation of its needs.

(vii) Purpose of the data to be gathered.

(33.1.2) Characteristics of participation.

(viii) Voluntary participation.

The voluntary nature of their participation, which they may reject.

(ix) Phases, procedures, actions and instruments for gathering anonymous data.

The different actions they will be asked to perform, the procedures or instruments for obtaining the anonymous data and, if applicable, whether these instruments are validated by the scientific community

to be administered as foreseen. If they are not, or have been constructed ad hoc, the guarantees provided (authority of the person or persons that have adapted, constructed or revised them).

(x) Experimental, control and placebo group, as applicable.

If there is an experimental group, control group or placebo group, the possibility that they may be included in one of these and the procedures for distributing each participant in the different groups.

(33.1.3) Risks, discomfort, benefits and responsibilities.

(xi) Risks and discomfort.

Possible risks or discomfort resulting from their participation in the research. When using instruments for obtaining data containing questions that may be uncomfortable or intrusive, they shall be informed and provided with the necessary resources for minimising these risks or discomfort. If no risks and discomfort are foreseen, this shall be indicated.

(xii) Benefits.

In the section on needs, objectives and hypotheses, an explanation shall be provided of the possible benefits in terms of scientific knowledge, society in general or a particular group of people. Despite the benefits generated by a research project not always being immediately enjoyed by the participants in the study, it is necessary to identify, as applicable, the potential benefits for participants or clearly indicate that there will be no benefits.

If the participants are not expected to see any benefits, what is known in the world of health as *therapeutic ambiguity* shall be avoided, in other words, the belief that the participant will experience an improvement in their health if they participate in the research, despite this not being the case.

(xiii) Responsibilities for the expected risks and discomfort, as applicable.

If applicable, the participants shall be informed of the measures for reporting, reacting to and assuming responsibility in terms of the expected risks and discomfort (for example, civil liability insurance).

(xiv) Responsibilities for any unexpected harm and discomfort, as applicable.

The commitment for appropriately responding in the event of any unexpected harm and discomfort caused by participation in the research shall be acquired (for example, professional assistance).

(33.1.4) Anonymous data protection.

(xv) Security measures when collecting, processing and storing anonymous data.

(i) Name of the organisation responsible for collecting, processing and storing anonymous data.

(xvii) Name of the researcher specifically responsible for collecting, processing and storing anonymous data.

(33.1.5) Communicating the research results.

(See point 3.6).

(33.2) Contents of the consent part.

As indicated in point 10.3.ii on anonymous consent, when anonymous data is gathered, for example, through an anonymous survey or questionnaire, consent shall be given when answering the survey or questionnaire; by refusing to answer, the potential respondent refuses to give their consent. Therefore, no nominal consent shall be requested that makes it possible to identify those who have participated in the research. Therefore, of the two parts of the informed consent document (information and consent), only the first should appear.

(34) When gathering personal data.

(34.1) Contents of the informational part.

Information shall be provided, adapting it truthfully, honestly and reasonably to the characteristics of each research process and invitation to participate in the study (face to face, over the phone, online, etc.), about the following:

(34.1.1) General information.

(i) Name of the research project.

(ii) Invitation for the person or organisation to participate in the research.

(iii) Name of the principal researchers, email address and contact phone number.

(iv) Organisation at which the research project is being conducted.

(v) Sources of funding, as applicable.

(vi) Aims and hypotheses of the project and a brief explanation of its needs.

(vii) Purpose of the data to be gathered.

(34.1.2) Characteristics of participation.

(viii) Voluntary participation and withdrawal.

The voluntary nature of their participation, which they may reject. That they may withdraw from the research at any time without the need to provide any explanation, without this being of any detriment to them.

(ix) Forced removal, as applicable.

Where relevant, the possibility that the person may be removed from the research if they fail to satisfy the established requirements or any reason that hinders the study.

(x) Phases, procedures, actions and instruments for gathering personal data (see point 33.1.2ix).

(xi) Experimental, control and placebo group, as applicable (see point 33.1.2x).

(34.1.3) Risks, discomfort, benefits and responsibilities.

(xii) Risks and discomfort (see point 33.1.3xi).

(xiii) Benefits (see point 33.1.3xii).

(xiv) Responsibilities for the expected risks and discomfort, as applicable (see point 33.1.3xiii).

(xv) Responsibilities for any unexpected harm and discomfort (see point 33.1.3xiv)

(34.1.4) Personal data protection.

(xvi) Security measures when collecting, processing and storing anonymous data.

(xvii) Anonymisation, pseudonymisation and self-chosen pseudonymisation procedure, as applicable (see point 23iii).

(xviii) Who will have access to personal data or correlation tables (see point 23ii).

(xix) Limitation of the purpose.

That the personal data shall not be used for purposes other than those for which consent was obtained from the participants (see point 24).

(xx) Name of the organisation responsible for collecting, processing and storing personal data and contact for the exercise of the corresponding rights (see point 23iv).

(xxi) Name of the specific researcher responsible for collecting, processing and storing personal data and contact for the exercise of the corresponding rights (see point 23v).

(xxii) Where to obtain more information on the processing and storing of personal data (see point 23vi).

(xxiii) Commitment to confidentiality and professional secrecy of the researchers and compliance with the provisions of the GDPR and LOPDGDD (see point 3.2).

(xxiv) Storing time and destruction process of personal data (see point 23vii).

(34.1.5) Communicating the research results.

(See point 3.6).

(34.2) Contents of the consent part.

When consent is nominal (see point 10.3i on types of consent), the informational part is followed by the informed consent part, which must be signed by the person or, as applicable, their legal representative, confirming that:

(i) They have been correctly informed, that they have been able to ask all the questions they consider appropriate, answers have been given

and that they have been provided with enough time to make a decision.

(ii) They understand that their participation is voluntary and that they can withdraw from the research at any time, without the need for providing explanations and without this having any impact on the assistance they receive or may receive.

(iii) The full name, national identity document number (if applicable) and the signature of the authorising party or parties shall be reflected.

As indicated in point 10.3i on consent and legal consent, whenever possible, consent shall be obtained from the person invited to participate, even though their legal consent is not required (children, adolescents or persons subject to legal support or protection measures).

(iv) The full name, national identity document number (if applicable) and the signature of the researcher who has provided the information and requested consent shall be reflected.

Nominal consent must be given, not refused. Using phrases like "I do not give my consent" shall be avoided, as they require the person to officially refuse to provide their consent and, unless they do so, this may be interpreted as passive or tacit consent.

Nominal consent shall be adapted truthfully, honestly and reasonably to the characteristics of each research process and invitation to participate (face to face, over the phone, online, etc.):

INFORMED CONSENT DOCUMENT (ORGANISATIONS). ASPECTS TO BE ASSESSED.

As indicated in point 11, when gathering data at an organisation or within their scope of responsibility, informed authorisation must be obtained from this organisation.

The informed authorisation document must address and consider the matters indicated below:

(35) Language and treatment.

(i) The information and consent shall be drafted in the official languages of the location in which the data is gathered.

(ii) The information and consent shall be written in a clear language that is easily understandable to the persons it is aimed at. The use of acronyms and technical language shall be avoided insofar as possible.

(iii) The language is respectful and treatment is formal.

(36) When gathering anonymous data

(36.1) Contents of the informational part.

(36.1.1) General information.

(i) Name of the research project.

(ii) Request for the organisation to authorise the research being conducted at their organisation.

(iii) Name of the principal researchers, email address and contact phone number.

(iv) Organisation at which the research project is being conducted.

(v) Sources of funding, as applicable.

(vi) Aims and hypotheses of the project and a brief explanation of its needs.

(vii) Purpose of the data to be gathered.

(36.1.2) Characteristics of participation.

(viii) Voluntary participation of the persons.

(ix) Voluntary authorisation of the organisation for the research to be conducted at their institution.

(x) Phases, procedures, actions and instruments for gathering anonymous data.

(xi) Experimental, control and placebo group, as applicable.

(36.1.3) Risks, discomfort, benefits and responsibilities.

(xii) Risks and discomfort.

(xiii) Benefits.

(xiv) Responsibilities for the expected risks and discomfort, as applicable.

(xv) Responsibilities for any unexpected harm and discomfort, as applicable.

(36.1.4) Anonymous data protection.

(Xvi) Security measures when collecting, processing and storing anonymous data.

(xvii) Name of the organisation responsible for collecting, processing and storing anonymous data.

(xviii) Name of the researcher specifically responsible for collecting, processing and storing anonymous data.

(36.1.5) Communicating the research results.

(36.2) Contents of the consent part.

(i) They have been correctly informed, that they have been able to ask all the questions they consider appropriate, answers have been given and that they have been provided with enough time to make a decision.

(ii) Their authorisation is voluntary and may be withdrawn if they believe there are reasons for doing so.

(iii) The full name, national identity document number (if applicable) and the signature of the authorising party or parties shall be reflected.

(iv) The full name, national identity document number (if applicable) and the signature of the researcher who has provided the information and requested authorisation shall be reflected.

(37) When gathering personal data.

(37.1) Contents of the informational part.

(37.1.1) General information.

(i) Name of the research project.

(ii) Request for the organisation to authorise the research being conducted at their organisation.

(iii) Name of the principal researchers, email address and contact phone number.

(iv) Organisation at which the research project is being conducted.

(v) Sources of funding, as applicable.

(vi) Aims and hypotheses of the project and a brief explanation of its needs.

(vii) Purpose of the data to be gathered.

(37.1.2) Characteristics of participation.

(viii) Voluntary participation and withdrawal of the participants and organisation.

(ix) Forced removal, as applicable.

(x) Phases, procedures, actions and instruments for gathering personal data.

(xi) Experimental, control and placebo group, as applicable.

(37.1.3) Risks, discomfort, benefits and responsibilities.

(xii) Risks and discomfort.

(xiii) Benefits.

(xiv) Responsibilities for the expected risks and discomfort, as applicable.

(xv) Responsibilities for any unexpected harm and discomfort.

(37.1.4) Personal data protection.

(xvi) Security measures when collecting, processing and storing anonymous data.

(xvii) Anonymisation, pseudonymisation and self-chosen pseudonymisation procedure, as applicable.

(xviii) Who will have access to personal data or correlation tables.

(xix) Limitation of the purpose.

(xx) Name of the organisation responsible for collecting, processing and storing personal data and contact for the exercise of the corresponding rights.

(xxi) Name of the specific researcher responsible for collecting, processing and storing personal data and contact for the exercise of the corresponding rights.

(xxii) Where to obtain more information on the processing and storage of personal data.

(xxiii) Commitment to confidentiality and professional secrecy of the researchers and compliance with the provisions of the GDPR and LOPDGDD.

(xxiv) Time limits for personal data storage and destruction process.

(37.1.5) Communicating the research results.

(37.2) Contents of the consent part.

(i) They have been correctly informed, that they have been able to ask all the questions they consider appropriate, answers have been given

and that they have been provided with enough time to make a decision.

(ii) Their authorisation is voluntary and may be withdrawn if they believe there are reasons for doing so.

(iii) The full name, national identity document number (if applicable) and the signature of the authorising party or parties or the organisation's data shall be reflected.

(iv) The full name, national identity document number (if applicable) and the signature of the researcher who has provided the information and requested authorisation shall be reflected.

APPENDICES

Rubric.

See the rubric in Excel format for this document.

Codes, manuals and protocols of good ethical and scientific practice.

A number of these ethical best practice codes indicated below are less demanding than those indicated in this Guide.

Academy of Social Sciences (2015). *General ethics principles for social science research.* https://www.acss.org.uk/developing-generic-ethics-principles-social-science/academy-adopts-five-ethical-principles-for-social-science-research/

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American Association for Public Opinion Research (AAPOR). *Code of Ethics.* https://www.aapor.org/Standards-Ethics/AAPOR-Code-of-Ethics.aspx

American Psychological Association (2017). *Ethical Principles of Psychologists and Code of Conduct.* https://www.apa.org/ethics/code.

World Medical Association (2013). *Declaration of Helsinki of the World Medical Association. Ethical principles for medical research involving human subjects.* https://www.wma.net/es/policies-post/declaracion-de-helsinki-de-la-amm-principios-eticos-para-las-investigaciones-medicas-en-seres-humanos/.

Association of Social Anthropologists of the UK and the Commonwealth (ASA) (2011). *Ethical Guidelines for good research practice* by. https://www.theasa.org/downloads/ASA%20ethics%20guidelines%202011.pdf.

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Catalan Data Protection Authority (APDCAT). *Guia pràctica. Avaluació d'impacte relativa a la protecció de dades* taken from (https://apdcat.gencat.cat/web/.content/03-documentacio/Reglament_general_de_proteccio_de_dades/documents/Guia-Practica-avaluacio-impacte-proteccio-de-dades-2019.pdf).

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Danish Connnittee on Scientific Dishonesty Guidelines for Good Scientific Practice (2009). *Guidelines for Good Scientific Practice*. https://ufm.dk/en/publications/2009/the-danish-committees-on-scientific-guidelines-for-good-scientific-practice.

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Emmanuel College. Committee for the Protection of Human Participants in Research (CPHPR). Policies and Procedures. https://www.emmanuel.edu/academics/research-at-emmanuel/committee-for-the-protection-of-human-participants-in-research.html

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DETAILED SUMMARY

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