Deusto
Comité de Ética en Investigación

GUIDANCE ON APPLYING FOR RESEARCH ETHICAL APPROVAL

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1. When and How to Apply for Research Ethical Approval

Although all research projects must consider ethical issues, not all of them require an ethical review report from the Research Ethics Committee at the University of Deusto (UD-REC). In general:

A research project **DOES require ethical approval** if it is:

- A research project involving human participants or personal data[1]
- A research project involving living beings or their biological samples.
- A research project previously assessed by the UD-REC that has undergone changes in the project that require a new ethical review.
- A research project in which participation may involve some form of risk (e.g., emotional discomfort when responding to questionnaires).
- A research project involving the recording of individuals in non-public places (e.g., qualitative studies recording interviews).

[1] For the definition of personal data, see section 5.1. Processing of personal data.

- A research project involving individuals with limited autonomy (minors, people with disabilities, etc.).
- A research project involving individuals who refer to the institution where they work (e.g., managerial staff in companies). In these cases, even if personal data are not collected, consent granted will need to be reviewed.
- For Bachelor's and Master's dissertations, see specifically section 2. Ethical suitability of Bachelor's and Master's dissertations.
- Prior to any request, applicants should consider two aspects: whether they have the skills and competence to carry out the research and the potential benefits (ethical, social, etc.) that the research will bring if conducted. If the answer is negative to either of the two questions, the terms of the research should be reconsidered. This reflection is particularly relevant in the case of Bachelor's and Master's dissertations.

A research project **does NOT require ethical approval** if it involves:

- A theoretical research project
- A research project not involving the direct participation and/or involvement of individuals, either face-to-face or remotely.
- A research project involving anonymised data that do not entail any risk for participants.
- A research project involving secondary sources.
- A research project involving individuals already evaluated by the UD-REC, which does not have any changes with respect to the project already assessed.
- A research project registered at a university other than the UD.
- A thesis project whose research plan has not yet been approved.

It should be noted that **scientific journals often require a suitability report prior to the publication of articles**. This report cannot be issued once the research is concluded. Therefore, if the publication of the project results is planned, the mandatory report must be requested before data collection begins, even if it is one of those projects that does not require ethical evaluation.

In the event that the project requires ethical approval, the **time** to request it will be:

- In the case of PhDs: once approved in the Research Plan.
- If it is a Bachelor's or a Master's dissertation: during the proposal phase, after the pre-assessment by the supervisor of the need to submit the project for ethical evaluation.
- In the case of other research projects, always before data collection.

As mentioned above, the ethical review **procedure** must be initiated by the research supervisor in the case of doctoral theses, Bachelor's or Master's dissertations or the designated supervisor in the case of other research projects by completing an application form for research ethical approval. This must be submitted together with the required documentation (see 6.Supporting documentation to be provided with the application form) to comite.etica@deusto.es. It should be noted that research plans submitted directly by doctoral students will not be assessed.

The project must be endorsed by the relevant Faculty in accordance with the research project approval procedure laid down by the relevant Vice-Rector's Office for Research.

For research previously assessed by the UD-REC, a new project report will be required instead of an ethical review request. This report should highlight any modifications to the original project that may affect ethical and data protection issues.

The REC meets once a month to evaluate the requests received by the Committee up to the last day of the previous month.

2. Ethical Suitability of Bachelor's and Master's dissertations

Both Bachelor's and Master's dissertations must meet the same ethical requirements as any other research conducted at the University of Deusto. Therefore, they require a suitability report from the Research Ethics Committee, except in the following cases:

- Theoretical study
- Study without participation and/or involvement of individuals
- Study using secondary sources
- Research with and/or about individuals already evaluated by the Research Ethics Committee (REC-UD), with no changes to the project
- Study with open science data
- Studies that, although using primary data, do not include vulnerable groups, nor process or collect sensitive data.

The following personal data are considered 'sensitive' and are subject to specific processing conditions:

- Personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs,
- Trade union membership,
- Genetic data, biometric data processed solely to identify a human being,
- Health data,
- Data related to a person's sexual life or sexual orientation.

When approving topics for these projects, the relevant parties (supervisors, Master's directors) must carefully consider:

- Whether the student has the competence to carry out the research and the potential benefits (ethical, social, etc.) the research will bring if conducted. If the answer is negative to either of these questions, the terms of the research should be reconsidered.
- The challenge for a student in obtaining the suitability report within a short time frame and being able to carry out a project with ethical risks, while ensuring that these risks are properly addressed.
- The increased complexity of ethical evaluation in cases where data is collected from patients or about health, or where the project involves the development of a medical product. In such cases, the research must also be evaluated by an external health committee, independent of the University of Deusto (see section 3. Ethical suitability of projects involving medicines, medical products, and/or health data).

For all these reasons, **it is recommended that these projects** fall within the situations outlined above: **not involving sensitive data or vulnerable individuals, and being exempt from ethical**

risks and the need for ethical evaluation. Thus, if personal data (clinical data, interview results, etc.) are used, **they should come from research projects that have already obtained the ethical suitability report**.

3. Ethical Suitability of Projects Involving Patients, Medicines, Medical Products, and/or Health Data

In the case of projects involving patients, medicines, medical products, and/or health data, there are certain situations in which it is mandatory for the research project to be evaluated by the corresponding certified external Ethics Committee affiliated with the Department of Health of the Basque Government.

- When the subject of the research is a patient;
- When the research involves medicines or medical products;
- When clinical records are reviewed or patient data are collected for research purposes;
- When biological samples are used.

The **Basque Country Research Ethics Committee for Medicines (CEIm-E)** will evaluate:

- Studies involving medicines and/or medical products;
- Multi-centre studies involving biological samples and/or health data in which recruitment and/or testing of patients/volunteers will take place at Osakidetza healthcare centres or private healthcare centres.

The procedure for requesting ethical evaluation from the Basque Country Medicines Research Ethics Committee can be found on the following website: **Clinical Research Ethics Committee – Research and Training – Basque Government**

The **Osakidetza Research Ethics Committee** will evaluate:

- Single-centre studies involving biological samples and/or health data in which patient/volunteer recruitment will take place at Osakidetza healthcare centres or private healthcare centres.

For research conducted in Biscay, the OSI Ezkerraldea-Enkarterri-Cruces Research Ethics Committee will be responsible for evaluating the project. The procedure for requesting project evaluation can be found in the following document (from page 28 onwards), and its contact email is CEINVEST.EECRUCES@osakidetza.eus.
For research in Gipuzkoa, the competent authority will be the Research Ethics Committee of the Integrated Health Organisation of Gipuzkoa, which can be contacted via email at: iratxe.urretabarallobre@osakidetza.eus.

The various ethics committees for research involving human beings (CEImE, local RECs, and the University of Deusto's REC) maintain confidential and ongoing communication regarding the evaluation and monitoring of the studies and research projects conducted within the community.

4. Information required to obtain ethical approval

The **nature and extent** of the information required in this procedure will vary according to the ethical risks of the project. For example, the involvement of individuals in the research can range from answering a questionnaire with non-sensitive information to providing biological samples. Any research involving personal data must at least meet the requirements of the Data Protection Act and requires ethical approval. However, **additional information** will also be required for certain projects, as summarised in the table below.

DOES THE PROJECT INCLUDE ANY OF THE FOLLOWING?	YES	INFORMATION SHOULD BE PROVIDED ON:
Data protection / personal / sensitive information[2] / data from minors etc.		● Personal data to be used. ● Planned procedures to safeguard data confidentiality. ● Assessment of the potential ethical implications of the proposed research or the expected scientific results.
Social interventions with ethical implications [3]		
Interactions with persons and/or institutions with ethical implications		
Data protection regarding genetic information		● Proposed number of patients/service users, selection criteria, and protocols. ● Statistical design of the experimentation. ● Type of samples proposed to be used. ● Assessment of the potential ethical implications of the proposed research or the expected scientific results.
Human experimentation		
Animal experimentation		
Use of biological agents posing health risks		
Use of tissues or biological samples of human origin		

The research team must ensure that the required information is adequately explained in the application form and/or the supporting documentation. The following sections outline the information that should be included in the application form, the project proposal and supplementary documentation.

2 In accordance with current legislation, sensitive data include personal information revealing racial or ethnic origin, political opinions, ideology, religious or philosophical beliefs, trade union membership, genetic and biometric data processed solely for the purpose of identifying a human being, as well as data concerning health, sexual life, sexual orientation, and criminal convictions or offences.

3 Behavioural studies, observational research, fieldwork, archaeological studies, interviews, life histories, questionnaires, and similar activities.

5. Application form

The application form is structured as a **questionnaire**, enabling researchers to systematically review relevant aspects. It provides sections for indicating how these aspects are addressed in the project, as well as the page or section of the project report where the evaluator can find the corresponding explanation.

In this Guide, the items of the questionnaire are presented below, along with a brief explanation to assist in completing the questionnaire.

5.1. Processing of Personal Data
5.2. Other Issues Related to Data Processing
5.3. Research Participant Information Sheet
5.4. Research Participant Informed Consent
5.5. Other Ethical Issues regarding Research Project Development
5.6. Participation of other Institutions or Research Centres in the Project

5.1. Processing of Personal Data

A large part of the research carried out in the UD uses data from individuals (obtained through interviews, questionnaires, the development of pilot projects, etc.).

Firstly, to ensure the proper application of regulatory provisions, it should be **determined whether a project involves the processing of personal data** in accordance with European Regulation 2016/679 on Data Protection and Organic Law 2/2018 of 5 December on the Protection of Personal Data and the Guarantee of Digital Rights. Personal data are defined as any information relating to identified or identifiable natural persons, with the key factor being that the information, either alone or in combination with other data, can be used to identify a specific individual, either because they are directly identified through certain data, or because they can be identified by other means. Personal data include both those obtained directly from the individual, as they provide them themselves, as well as data generated by the individual (their mobility or health), or evaluative reports conducted on specific individuals, for instance.

A person will be considered **identified** when the database contains information that allows them to be distinguished from other individuals whose data have been collected, and it is possible to link any of that data to a specific individual (either through personal details, identification document, or a code).

An identifiable person is someone who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to or characteristic of their physical, physiological, mental, economic, cultural or social identity.

Conversely, data protection regulations do not apply to information that is managed anonymously in such a way that the individual can no longer be identified, nor can the process be reversed to identify them, while ensuring that their identification is prevented. Data protection regulations define the process of dissociation or anonymisation as any treatment of personal data in such a way that the information cannot be associated with an identified or identifiable person. Research using anonymous data, where the information cannot, in any way, be linked to any individual, should not be considered research involving 'sensitive' personal data.

They lose their 'personal' character. However, an ethical review will still be required in cases where the research involves any type of risk to participants (for example, emotional discomfort when responding to a questionnaire).

In many projects, **pseudonymisation** criteria are applied, which involve removing or delimiting specific information that could identify individuals, with the goal of eliminating, in an irreversible manner, any possibility of identification and preventing re-identification when the data are reused. Anonymisation of data should be viewed as a method of eliminating the possibility of identifying individuals in a research project, offering stronger privacy guarantees. In this context, the use of a code for each individual should be considered, ensuring that data cannot be linked back to any participant. The relationship between personal identity and the code will be securely maintained by the data custodians of the research project in strict confidentiality.

Pseudonymisation allows for re-identification of individuals in cases where it is essential, but this access is limited and specific. The application of pseudonymisation techniques requires prior definition of the technical mechanisms necessary for implementation. This process does not exempt researchers from complying with the relevant personal data protection regulations when handling the information.

Effective management of personal data protection issues will require research teams to first address the following questions, which will help assess the data management risks posed by their projects. This questionnaire will also assist projects in defining the appropriate internal processes for identifying data use and implementing suitable data management measures:

1. Does the project involve the collection and use of personal information about the participants as research subjects? (Yes/No)

2. Does the proposed research project require the creation of personal databases, such as conducting surveys, studies, research, and similar activities? (Yes/No)

3. Does the proposed research project collect, use, analyse or process any of the following personal data?

- Personal data concerning an identified or identifiable natural person, such as identity or identifying information like name and surname, official identification document, National Insurance number or equivalent, telephone number, address, signature, username, IP address, or other identifiers (Yes/No).
- Personal characteristics of an individual such as physical traits, preferences, hobbies, date of birth, nationality, gender, family circumstances such as number of children, housing, or similar. (Yes/No)
- Personal financial data, such as business activities, income, revenues, banking information, or similar. (Yes/No)

If yes, what measures have been taken to address them? Where in the project are they developed? [4]

4. Does the proposed research project collect, analyse, use or process personal data relating to employment information, academic and professional data, job position, training, qualifications or similar circumstances? (Yes/No)

4 For all questions that require it, the relevant sections of the report or submitted documentation should be copied here, along with the page number where they can be found.

If yes, what measures have been taken to address them? Where in the project are they developed?

5. Does the proposed research project collect, analyse, use or process personal data relating to consumption data on supplies, food, consumption habits, behavioural, usage or consumption profiles or other similar data? (Yes/No)
If yes, what measures have been taken to address them? Where in the project are they developed?

6. Does the proposed research project deal with any special category data?

- Ethnic or racial origin (Yes/No)
- Political opinions, religious or philosophical beliefs (Yes/No)
- Genetic, biometric or health data (Yes/No)
- Sexual life or orientation (Yes/No)
- Trade union membership (Yes/No)

If the project handles these special category data, what measures have been taken to address them? Where in the project are they developed?

7. Does the proposed research project collect, use, analyse or process:

- Medical reports and/or medical records (Yes/No)
- Disability, mobility and/or autonomy of the individual (Yes/No)
- Addictions and/or substance use (Yes/No)
- Mental illness and/or psychological care (Yes/No)
- Alcohol consumption and/or smoking (Yes/No)
- Circumstances similar to the above? (Yes/No)

If yes, what measures have been taken to address them? Where in the project are they developed?

8. Does the proposed research project collect, use, analyse or process personal data that analyse or make psychological or behavioural assessments? (Yes/No)
If yes, what measures have been taken to address them? Where in the project are they developed?

9. Does the proposed research project collect, use, analyse or process personal data linked to:

- gender-based violence or violence against women (Yes/No)
- child to parent violence (Yes/No)
- bullying, cyberbullying, grooming or other similar forms of violence (Yes/No)
- other forms of violence (Yes/No)?

If yes, what measures have been taken to address them? Where in the project are they developed?

10. Does the proposed research project envisage the participation of groups such as minors, individuals over 65 years of age, people with illnesses or specific diseases, groups at risk of social exclusion, other groups of particular sensitivity, vulnerable individuals or people who have not given their explicit consent to participate in the project? (Yes/No)
If yes, what measures have been taken to address them? Where in the project are they developed?

11. Does the proposed research project collect, use, analyse or process personal data related to time and attendance, or access control through video surveillance or biometric control systems? (Yes/No)
If yes, what measures have been taken to address them? Where in the project are they developed?

12. Does the proposed research project collect, use, analyse or process personal data involving the geolocation of individuals through automated devices? (Yes/No)
If yes, what measures have been taken to address them? Where in the project are they developed?

13. Does the proposed research project collect, use, analyse or process personal data related to criminal records, convictions or sanctions? (Yes/No)
If yes, what measures have been taken to address them? Where in the project are they developed?

5.2. Other Issues Related to Data Processing

14. Does the proposed research project use or process large volumes of data? (Yes/No)
If yes, what measures have been taken for their processing? Where in the project are they developed?

15. Does the proposed research project involve multiple datasets and/or service providers? (Yes/No)
Does the proposed research project involve other public or private entities such as public administrations, foundations or other private companies? (Yes/No)
Does the proposed research project rely on the combination and analysis of different data sets (big data)? (Yes/No)
If yes, what measures have been taken to address them? Where in the project are they developed?

16. Are any of these entities involved in the proposed research project?

- public or private entities located in other EU countries (Yes/No)
- public or private entities located outside the European Union? (Yes/No)

Is there any transfer of personal data to non-EU countries? (Yes/No)
Are personal data collected outside the European Union? (Yes/No)
If yes, where in the project is the role of these institutions developed?

17. Does the proposed research project use technological tools or applications that collect, process, or handle personal data, such as cloud applications, software outside the University of Deusto, repositories on external technology platforms, or similar? (Yes/No)
If yes, where in the project are they developed?

18. Is Artificial Intelligence used in the proposed research project to analyse personal data? (Yes/No)
Is automated decision-making used that has a significant impact on the data subjects? (Yes/No)

If yes, where in the project are they developed?

19. Are the following data collection or processing techniques used in the proposed research project?

- methods or technologies that invade privacy (e.g. covert observation, surveillance, tracking, or deception of individuals) (Yes/No)
- camera systems to monitor behaviour or record sensitive information (Yes/No)
- web crawling or social media analysis? (Yes/No)

If yes, where in the project are they developed?

20. Is profiling being conducted for individuals or groups, particularly behavioural or psychological profiling? (Yes/No)
If the answer is yes, in which part of the project are they developed?

21. Does the proposed research project involve multiple datasets and/or service providers? (Yes/No)
Does the proposed research project involve other public or private entities such as public administrations, foundations or other private companies? (Yes/No)
Does the proposed research project involve the combination and analysis of different datasets (big data)? (Yes/No)
If yes, what measures have been taken to address them? Where in the project are they developed?

22. Is it necessary to apply anonymisation techniques to personal data without using the identity data of the participants? (Yes/No/Not applicable)
If yes, how is it proposed or explained in the project?

23. Are techniques or processes used to dissociate or encrypt personal data so that the information obtained cannot be associated with an identified or identifiable individual, for example, by assigning a code to each individual? (Yes/No/Not applicable)
If yes, how is it proposed or explained in the project?
If applicable, is the relationship between personal identity and assigned code preserved by the data custodians of the research project? (Yes/No/Not applicable)
If preserved, how is it proposed or explained in the project?

24. Is the procedure for handling sensitive information, along with the mechanisms to ensure confidentiality, privacy, and data protection during the implementation of the project and after its completion, clearly outlined? (Yes/No)
If outlined, how is it proposed, or where in the project is it explained?

25. Is there a plan to use the data collected in the proposed research project for other separate projects? (Yes/No)
If yes, how is it proposed, or where in the project is it explained?

26. For how long are the project data expected to be stored? Where in the project is this explained? If applicable, for what purpose will the data be retained after the project is completed? What systems or safeguards will be used to retain these personal data? Will the data be kept locked or anonymised?

27. Do you know if the role assumed by the University of Deusto in matters of Personal Data Protection has been clearly defined? (Yes/No)
If yes, what is it/where in the project is it explained?

5.3. Research Participant Information Sheet

In research involving interventions with human participants or personal data, it will be necessary to provide research participants with an Information Sheet. The Committee has prepared an template for drafting participant information sheet for research involving human participants, which must be downloaded and customised for each specific case. The Committee will ensure the document includes all the necessary information by addressing the following questions:

28. Does the proposed research project require that participants be provided with an information sheet? (Yes/No)
If yes, does it include the following aspects?
Introduction: This section specifies who is leading the proposed research and explains the purpose of inviting them to participate in the study. Participants are informed that they can discuss the research with someone they feel comfortable with and are encouraged to take as much time as they need to decide whether or not they wish to participate. They are assured that if any terms or concepts are unclear, explanations will be provided, and that they can ask questions either now or at a later time. (Yes/No)
Purpose of the research: This section explains the goals and necessity of the proposed research in simple, non-technical language. The language should be clear and straightforward, helping participants understand what is expected of them without causing confusion. Local and easily understood terms should be used, and there are online resources available to help replace technical or research-specific terms with more accessible alternatives. (Yes/No)
Type of Research Intervention: The type of intervention/participation requested is briefly explained. (Yes/No)
Participant selection criteria: This section outlines the criteria for selecting participants. t is important to address any concerns participants may have about why they were chosen, as they might feel uncertain, confused, or even anxious about their involvement in the study. (Yes/No)
Voluntary participation: It is clearly stated that they may choose to participate or not, and they may withdraw at any time without giving any reason. It is important to clearly establish from the outset that participation is voluntary and ensure that all information about the proposed research is understood within this context. (Yes/No)
Procedures and protocol: This section outlines the exact procedures that will be used, explained step by step, the tests that will be conducted and all relevant information related to the proposed research. The procedures and their significance are explained clearly from the outset. Participants should know what to expect and what is expected of them. (Yes/No)
Duration: This section explains the time commitment required from participants in the proposed research, including both the duration of the study and any relevant follow-up. (Yes/No)
Risks: A risk can be defined as the possibility of harm occurring. Sufficient information about the risks is provided so that participants can make an informed decision, including details about the level of care that will be available in the event of harm, who will provide it, and who will assume responsibility. (Yes/No)
Benefits: Any benefits to the research participants should be stated clearly. The benefits can be divided into benefits for the individual, benefits for the community in which the individual resides, and benefits for society as a whole resulting from finding an answer to the research question. (Yes/No)

Incentives: It is clearly stated what participants will receive for their participation. While incentives are not recommended, reimbursement for expenses incurred as a result of participating in the research, if any, is encouraged. (Yes/No).
Data storage and safeguarding: This section specifies where and how information will be securely stored, ensuring that no person outside the research team has access throughout the research duration. The person responsible for data security is also identified. (Yes/No)
If personal data are collected or included, specific measures must be detailed regarding how these data will be managed: This should include how the data will be collected; whether they will be stored digitally and on which platforms or storage systems; who will be responsible for the files; and who will have access to them. Whether data will be transmitted to third countries (e.g., as part of international projects) or shared with third-party services involved in the project, the recipients of these data must be specified. The duration of data retention should be outlined, along with anonymisation procedures for scientific publications and the methods to be used. Finally, it should explain how data will be handled once they no longer need to be retained, along with any other relevant information.
Confidentiality: It is fully explained how the research team will maintain the confidentiality of information, especially with regard to information about individual participants. (Yes/No)
Research results: Where relevant, the planned approach for sharing information with research participants is provided. If there is a plan for sharing information, details must be included. Participants should be informed that research findings will be disseminated more broadly, such as through publications and conferences. (Yes/No)
Right to withdraw: It is confirmed that participation is voluntary and that participants have the right to withdraw at any time without giving any reason. (Yes/No)
Right of access, rectification, erasure, restriction of processing, data portability, or objection to processing: Participants are informed that they may exercise their rights of access, rectification, erasure, restriction of processing, data portability, or objection to processing by contacting the Data Protection Officer at the University of Deusto via email at dpo@deusto.es. If applicable, they may also seek oversight from the Basque Data Protection Authority. (Yes/No)
Who to contact: The name and contact information of an informed, accessible individual who is part of the research are provided. (Yes/No).

5.4. Research Participant Informed Consent

Informed consent is a formal and necessary procedure that involves **obtaining a person's authorisation to participate in a research study. It requires providing** a clear, comprehensive, and unbiased **explanation** of all relevant **information** about the proposed research in which they will participate. Key elements include:

- Voluntariness: individuals must be able to **freely decide** whether or not they want to participate in a research project.
- Information: Each subject must receive the **minimum necessary information**, both verbally and in writing, to enable them to decide whether to participate in a particular research study.
- Competence or capacity: For informed consent to be valid, the individual must have the ability to **understand the information provided**. It is acknowledged that a person is considered competent when they can make decisions based on their knowledge, values, and personal goals, once the possible consequences of their decision are understood and analysed.

If minors are involved in the research, consent information should be provided to both the minors and their legal representatives, unless there is a valid reason not to do so (e.g., if the information could harm the minor). Ideally, both the minor and their representative should give consent, although only the adult representative will sign the document. The information should be adapted to the minor's capacity, maturity, and context.
In general, in research involving children between the ages of 12 and 14, it is mandatory to obtain the minors' assent. From the age of 14 onwards, the minor's consent, in addition to that of his/her representative or guardian, is mandatory if participation in the proposed research may entail risks. If there are no risks, because it is observational research in which confidentiality will be preserved, minors can give their consent from the age of 14 in our country and the consent of their representatives or guardians is not required.

In the case of research participants who are non-autonomous or not competent, **consent must be obtained from their legal representatives**, and the representative's status must be documented. If possible, the **participant's assent** should also be sought. Any project that collects or handles personal data in any form or model of management requires the research team to plan a framework for legitimising data use. Furthermore, any project involving the collection of personal data must obtain participants' consent for the collection, processing, and storage of their data. For health data, the provisions of Additional Provision 17 of the Organic Law on Data Protection and the Guarantee of Digital Rights (Official Spanish Gazette BOE 6.12.2018) must also be considered.

The Committee has developed a template for drafting informed consent for research involving human particpants, which should be downloaded and customised to each specific case. As a general rule, consent should be obtained in writing. However, in exceptional cases, verbal consent may be accepted. In such instances, it must be documented that consent has been obtained, and the reason for requesting oral consent instead of written consent must be justified in the report.

Accordingly, the following information will be required on the application form:
29. Does the proposed research require consent? (Yes/No)
Please provide reasons for your answer.

30. What form of consent is used (Written/Verbal/Other)?
If other, please explain.

31. Are participants informed about voluntariness? (Yes/No/Not applicable)
If yes, how is it addressed? Where in the project is it explained?

32. Do participants receive information about the possibility of withdrawing from the proposed research? (Yes/No/Not applicable)
If yes, how is it addressed? Where in the project is it explained?

33. Are participants informed about confidentiality, privacy and data protection during the implementation of the project and after its completion? (Yes/No/Not applicable)

34. Are participants informed of any potential risks? (Yes/No/Not applicable)
If yes, how is it addressed? Where in the project is it explained?

This question requires that the research project anticipates potential risks and harms, which may include the following as a guideline:

- Invasive and physically risky techniques
- Procedures or methods that may evoke traumatic experiences or subject the participant to significant stress.
- Procedures involving invasion of privacy, particularly interviews, questionnaires, and tracking of individuals, with greater impact if they involve sensitive data.
- Procedures involving social risk: those dealing with sensitive issues or capable of causing discrimination, social stigma, or personal or familial harm. Among others, and as indicative examples, these include topics related to political or religious ideology; sexual life; illegal or antisocial backgrounds; mental illnesses or severe psychological issues; data on violence, harassment, abuse, or active or passive physical, psychological, or sexual abuse. This section also includes vulnerable groups in the context of research involving individuals (minors, persons with disabilities, individuals at risk of social exclusion, incarcerated population, undocumented immigrants, etc.). If such topics are addressed or the project involves such individuals, it will likely require a privacy impact assessment, which the project must incorporate into its documentation; this will require the **involvement of an expert in data protection**.

35. Are measures clearly included to minimise the pain, stress, physical, or emotional risk to the research participants? (Yes/No/Not applicable)
If yes, how is it addressed? Where in the project is it explained?

36. Is it outlined how the needs and perspectives of the study participants will be considered? (Yes/No/Not applicable)
If yes, how is it addressed? Where in the project is it explained?

37. Is the procedure for handling sensitive information regarding individuals, data, etc. during the project and after its completion detailed? (Yes/No/Not Applicable)
If yes, how is it addressed? Where in the project is it explained?

38. Is information provided about the study objectives, lead researcher and contact details? (Yes/No/Not applicable)?
If yes, how is it addressed? Where in the project is it explained?

39. Is it stated whether participation in the proposed research project will be compensated or whether it will be voluntary? (Yes/No)
If yes, how is it addressed? Where in the project is it explained?

40. Is the language used adapted to ensure that the informed consent is clearly understood? (Yes/No)
If yes, how is it addressed? Where in the project is it explained?

41. Are mechanisms in place to address questions, concerns, and issues raised by participants during the research study? (Yes/No)
If yes, how is it addressed? Where in the project is it explained?

42. Is informed consent required from minors/persons with intellectual, cognitive or mental disabilities or difficulties? (Yes/No)

43. Is authorisation from the centre required? (Yes/Not applicable)

44. Is proxy consent required from guardians? (Yes/Not applicable)

45. Is consent required from minors over 14 years of age? (Yes/Not applicable)

46. Is assent required from participants over 12 years of age? (Yes/Not applicable)

47. Is assent required, if possible, from dependent persons? (Yes/Not applicable)

48. Is information provided in the consent document on the duration of the project and the data custodians? (Yes/Not applicable)

49. Does the consent document provide information on how the research results will be disseminated? (Yes/Not applicable)

50. Is the full contact information of the project leader (in the case of PhDs, the thesis supervisor) provided in the consent document? (Yes/Not applicable)

5.5. Other Ethical Issues regarding Research Project Development

Furthermore, additional methodological or project development aspects will be reviewed. The following information should be included in the ethical review application:

51. Are the objectives, justification, and ethical implications of the project clearly described in the report? (Yes/No)
If yes, how are they addressed, and where in the project are they explained?

52. Is the proposed methodology and its ethical implications clearly described in the report? (Yes/No)
If yes, how are they addressed, and where in the project are they explained?

53. Is it stated whether there will be a control group and how it will be managed during the project's development, detailing the ethical aspects related to its formation and participation in the study (e.g., randomisation to uphold the principle of equity)? (Yes/No)
If yes, how is it addressed? Where in the project is it explained?

54. Are the legal and ethical requirements of the country(ies) and/or institutions where the study will be conducted taken into account, with provisions to ensure compliance? (Yes/No)
If yes, how is it addressed? Where in the project is it explained?

55. Are risk factors identified for the integrity and/or independence of the proposed research? (Yes/No)
If yes, how is it addressed? Where in the project is it explained?

56. Are ethical requirements for project approval, development and accountability (pre- and post-implementation) incorporated into the work plan? (Yes/No)
If yes, how is it addressed? Where in the project is it explained?

57. Are risk factors to the integrity and/or independence of the proposed research identified? (Yes/No)
If yes, how is it addressed? Where in the project is it explained?

58. Are the ethical and social benefits of the proposed research project stated? (Yes/No)
If yes, how is it addressed? Where in the project is it explained?

59. Are there any restrictions on the publication of research results? (Yes/No)
If yes, how is it addressed? Where in the project is it explained?

60. Is there a provision for communicating the results to participants? (Yes/No)
If yes, how is it addressed? Where in the project is it explained?

61. Are there any other aspects of ethical relevance that should be mentioned? Please specify (e.g.: Have good practices been considered to avoid potential bias and cultural appropriation)? (Yes/No)

5.6. Participation of other Institutions or Research Centres in the Project

In those joint projects with other bodies or institutions (such as universities, research centres, associations, hospitals, etc.), alongside the application, ethical approval must be obtained from the Research Ethics Committee of the respective institution, authorising the development of the proposed research project, their participation in it, and/or the use of data or individuals related to those bodies.
In the event that another body or entity participates, when setting up the consortium, the role adopted by each institution in relation to data protection must be accurately defined, specifying whether the University of Deusto is the Data Controller, Data Processor or Joint Controller.

62. Are other institutions, centres, or research units involved in the proposed research project? (Yes/No)

63. Is approval from the RECs of the collaborating research centres/units required for the proposed research project? (Yes/No)
Remarks:
In the event that approval from the RECs of the other participating research centres/units is required, are such certifications/Ethics Committee Reports attached? (Yes/No)

6. Supporting Documentation to be Submitted with the Application

- Project Report: The report should adequately explain all aspects that have been positively indicated in the application form, as well as the following:
  - Aims of the research
  - The proposed methodology and techniques
  - The work plan
  - The expected impact on participants.
  - The expected risks as well as the proposed social ownership strategies.
  - Description of the procedure for managing personal data obtained once the project is completed.
  - Signed commitment by the project lead (or thesis supervisor) concerning the confidentiality of personal data and their intended use (for academic and/or scientific dissemination) during the project's development and once it is completed.
  - Specification of the compensations planned for the individuals involved in the project. If this option is not considered, it should be clearly stated in the project report.
  - Specification of the insurance taken out for voluntary participants, if required.
  - Other data of ethical interest of the project.

- If the research requires obtaining consent from participants: the information sheet template for participants and informed consent form to be used in the project should be provided.
- If there are other participating research centres/units and the approval from their Ethics Committees (CEDI) is required: certifications/reports from the Ethics Committee of other participating organisations in the project.

7. Obtaining a UD-REC report

The UD-REC will respond by email within a maximum of 4 weeks with an ethics review report, which will be:

- Favourable Report: This confirms that all requirements have been met.
- Pending Resolution: Issued when the submitted documentation lacks essential information for a positive or negative assessment of the project or research. A four-week period will be given to provide the required information/documentation. During this period, the project lead or thesis supervisor must send the requested materials to comite.etica@deusto.es. The project will be reassessed upon receipt of the information/documentation.
- Unfavourable Report: In this case, a new application and all corresponding documentation must be submitted.