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 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.

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).
- 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.
- A proposal for a Master's Final Project (MFP) involving students' contact with groups considered vulnerable in the field of research with individuals (minors, people with disabilities, people at risk or in situations of social exclusion, incarcerated population, undocumented immigrants, etc.).

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.
- In the case of Master's Final Projects: once the Master's Programme Coordinator has assessed whether the project needs to undergo ethical review.
- In the case of other research projects, always before data collection. It should be noted that scientific journals often require an ethical review report for the publication of articles. This report cannot be issued until the proposed research has been concluded. Therefore, in anticipation of this circumstance, the mandatory report must be requested before data collection for the proposed research.

The ethical review **procedure** must be initiated by the research supervisor in the case of doctoral theses, the Master's coordinator in the case of MFPs 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 4.Supporting documentation to be provided with the application form) to comité.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. Before they begin their ethics application, applicants should consider two issues: whether they have the competence to conduct the proposed research, and the benefits (ethical, social, etc.) it will entail if carried out.

[1] For the definition of personal data, see section 3.1. Processing of personal data.

If the answer is negative to either of these questions, the terms of the proposed research should be reconsidered. This reflection is particularly relevant in the case of Master's Final Projects.

2. Information required to obtain ethical approval

The **type and level of detail** of the information required in this procedure will vary according to the ethical risks of the project, (the involvement of individuals in the research can vary greatly, ranging from answering a questionnaire with non-sensitive information to providing biological samples, for example). 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.

<table>
<tr><th>DOES THE PROJECT INCLUDE ANY OF THE FOLLOWING?</th><th>YES</th><th>INFORMATION SHOULD BE PROVIDED ON:</th></tr>
<tr><td>Data protection / personal / sensitive information / data from minors etc.</td><td></td><td rowspan="3">● 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.</td></tr>
<tr><td>Social interventions with ethical implications [2]</td><td></td></tr>
<tr><td>Interactions with persons and/or institutions with ethical implications</td><td></td></tr>
<tr><td>Data protection regarding genetic information</td><td></td><td rowspan="5">● 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.</td></tr>
<tr><td>Human experimentation</td><td></td></tr>
<tr><td>Animal experimentation</td><td></td></tr>
<tr><td>Use of biological agents posing health risks</td><td></td></tr>
<tr><td>Use of tissues or biological samples of human origin</td><td></td></tr>
</table>

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

3. Application form

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

In this Guide, the items of the questionnaire are presented below with a brief explanation to facilitate the completion of the questionnaire.

3.1. 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 that the regulatory provisions have been properly applied, it should be **identified 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. This considers personal data to be any information concerning identified or identifiable natural persons, the decisive element being that the information, combined or by itself, allows **data on a specific person to be known**, either because they are directly identified through some data, or because they may become identifiable by other means. Personal data are both those obtained directly from the person because the latter provides them directly, as well as data generated by the person (their mobility or health), or evaluative reports carried out on specific persons, for example.

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

An identifiable person is one 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 his physical, physiological, mental, economic, cultural or social identity.

Conversely, data protection regulations will not apply to information managed anonymously in such a way that it is no longer possible to identify the individual, nor to reverse the process to identify them, while ensuring that their identification is prevented. The data protection regulations understand the process of dissociation or anonymisation as any treatment of personal data in such a way that the information obtained cannot be associated with an identified or identifiable person. Research with anonymous data that uses data from individuals, which cannot, in any way, be related to any person, should not be considered research involving

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

In many projects, **pseudonymisation** criteria are chosen to be applied, which involves delimiting and suppressing specific information that allows individuals to be identified, with the aim of eliminating, in an irreversible manner, the possibilities of identification and thus avoiding re-identification when the data are reused. The anonymisation of data should be considered as a way of eliminating the possibility of identifying individuals in a research project and should offer greater guarantees of privacy to individuals; in this case, the possibility of assigning a code to each individual should be considered, thus preventing the data from being available to any participant in the research project. The data regarding the relationship between personal identity and code will be kept by the data custodians of the research project in strict confidentiality.

Pseudonymisation allows for access to re-identify individuals in cases where it is essential, albeit limited and specific. The application of pseudonymisation techniques requires prior definition of the technical mechanisms required for implementation.

Effective management of issues related to the protection of personal data will require research teams to first address the following questions, which will allow to assess the information management risks posed by their projects; this questionnaire will also help projects to define internally the appropriate processes for identifying data use, and to put in place appropriate data management measures:

1. Does the proposed research project require the collection and use of personal information from individuals participating in the proposed research 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? [3]

[3] For all questions requiring it, an explanation must be provided and/or reference made to the page of the project report or supporting documentation where the information is included.

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)
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 consumptions (Yes/No)
- Mental illness and/or psychological care (Yes/No)
- Alcohol consumption and/or smoking (Y/N)
- 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, people over 65 years of age, sick people and specific diseases, groups at risk of social exclusion, other groups of special sensitivity, vulnerable people 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 the individual 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?

3.2. 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 a transfer of personal data to countries 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 operate with 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 the 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. Are profiles of individuals or groups drawn up, in particular profiles:

- 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?

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/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/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/explained in the project?

24. Is the procedure for handling sensitive information and the mechanisms to ensure confidentiality, privacy, and data protection during the project's implementation and after its completion outlined? (Yes/No)
If outlined, how is it proposed/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 indicated, how is it proposed/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?

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?

3.3. 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. It will be verified by answering the following questions:

28. Does the proposed research project require that participants be provided with a letter of information? (Yes/No)
If yes, does it include the following aspects?
Introduction: It 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 talk to someone they feel comfortable with about the research project and that they can take as much time as they wish to reflect on whether or not they want to participate. Participants are assured that if they do not understand some of the words or concepts, explanations will be provided; and that they can ask questions now or later. (Yes/No)
Aims: Information on the aims and need for the proposed research is provided to participants in lay language. The language used should aim to help participants understand what is expected of them rather than cause confusion. Local and simplified terms are used. There are guides on the internet to help find substitutes for exclusively scientific or research-specific words. (Yes/No)
Type of Research Intervention: The type of intervention/participation requested is briefly explained. (Yes/No)
Participant selection criteria: The criteria for selecting participants are explained. People may wonder why they are chosen to participate and may be frightened, confused or worried. (Yes/No)
Voluntary participation: It is clearly stated that they may choose to participate or not, and they may withdraw at any time without the need to provide an explanation. It is important to clearly establish at the outset that participation is voluntary so that all information about the proposed research is heard within this context of voluntary participation. (Yes/No)
Procedures and protocol: The exact procedures that will be used are 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 from the beginning. Participants should know what to expect and what is expected of them. (Yes/No)
Duration: An explanation is provided regarding the time commitments involved for 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. Enough information about the risks is provided so that participants can make an informed decision, indicating the level of care that will be available in the event of harm, who will provide it, and who assumes responsibility. (Yes/No)
Benefits: The actual benefits to research participants are highlighted. 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 as a result of 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: The location and procedure by which the information will be stored are specified, ensuring that no person outside the research has access, throughout the entire duration of the research, and the person who will be responsible is identified. (Yes/No)
If personal data are affected, collected, or included, specific measures for safeguarding the data must be included: How it will be collected; Whether it will be stored electronically; Who will be responsible for the database; Who will have access to the files; How long they will be retained; That it will be anonymised for scientific publications and how this will be done; and any other information considered relevant.
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)
Outcomes: Where relevant, the planned approach for sharing information with research participants is provided. If there is a plan for sharing information, details are 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 includes the right to withdraw (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).

3.4. 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, following an explanation of all** relevant, understandable, comprehensive, and unbiased **information** regarding the proposed research in which they are participating. It requires the following elements:

- Voluntariness: individuals must be able to **freely decide** whether they want to participate or not 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 **provided information must be understood**. It is acknowledged that a person is competent when they can make decisions based on their knowledge, values, and personal goals, once the possible consequences of their decision are known and analysed.
  If minors are involved in the research, the information for seeking consent should be given to both minors and their representatives, unless there is some reason not to do so (e.g. the information would harm the minor). It is most convenient that, after the information, both the minor and his/her representative give their consent, although obviously the document will be signed only by the adult person representing him/her. Such information should be adapted to the capacity, maturity and context of the minor.

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 event that research participants are non-autonomous or not competent, **consent must be obtained from their representatives** (the representative's status must be documented). If possible, the **subject's assent** must also be obtained. Any project that collects or handles personal data in any of its forms or management models requires team participants to plan a format for legitimising data use. Likewise, any project involving the collection of personal data must include participants' consent for the collection, processing, and storage of their data. In the case of health data, the provisions of Additional Provision 17 of the Organic Law on Data Protection and Guarantee of Digital Rights (Official Spanish Gazette BOE 6.12.2018) must also be taken into account.

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/Oral/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 if it is 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)

3.5. 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. Does the report describe the specific ethical issues affecting the project's objectives and how it plans to address them? (Yes/No)
If yes, how is it addressed? Where in the project is it explained?

52. Does the report describe the specific ethical issues affecting the proposed methodology and how it is intended to address them? (Yes/No)
If yes, how is it addressed? Where in the project is it 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 (for example, 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 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 taken into account to avoid possible bias, cultural appropriation, etc.)? (Yes/No)

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

In those joint projects with other bodies or institutions (universities, research centres, associations, hospitals, etc.), alongside the application, ethical approval must be obtained from the Research Ethics Committee of that 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)

4. 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 proposed research requires obtaining consent from the participants in the project: Participant Informed Consent Template to be used in the project.
    - If written informed consent is necessary: Information
    - Sheet for research participants to be used in the project.
    - 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.

5. Obtaining a UD-REC report

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

- Favourable Report: It determines that all requirements are met.
- Pending Resolution: When the documentation submitted shows the absence of essential data for positively or negatively assessing the project or research work concerned. A four-week deadline will be given to provide the relevant information/documentation. Within this period, the project lead or thesis supervisor must send the requested information/documentation to comite.etica@deusto.es, and the project will be assessed upon receipt of the information/documentation.
- Unfavourable Report: In this case, a new application and all corresponding documentation must be submitted.