

Innovative and Inclusive Democratic Spaces for Deliberation and Participation
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D6.1 Ethical Protocols

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Summary

This report presents the ethical guidelines and protocols that will be followed throughout the IDEM Project. It has been developed to inform and guide the consortium in the adoption of an ethical framework for research within IDEM. It guides IDEM partners to properly carry out research with the target groups in an informed and ethical manner.

Plain Language Summary

This report presents the ethical guidelines and protocols partners will follow in the IDEM Project. This report's objective is to inform and guide the consortium for research in an ethical framework. It guides IDEM partners to properly carry out research with the target groups in an informed and ethical manner.



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Author List		
Organisation	Name	Contact Information
UPF	Horacio Saggion	horacio.saggion@upf.edu
CIB	Lian Muñoz	lian.munoz@cibervoluntarios.org
AAIT	Claudia Mazzanti	claudia.mazzanti@actionaid.org
UPF	Sandra Szasz	sandra.szasz@upf.edu
UoL	Carlo Eugeni	c.eugeni@leeds.ac.uk
ANFFAS	Eleonora Severa	esevera@anffas.net
PIM	Almudena Rascón Alcaina	almudenarascon@plenamadrid.org
MAC	John O'Flaherty	j.oflaherty@mac.ie

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Acronyms	
ACM	Association for Computing Machinery
AI	Artificial Intelligence
ALLEA	All European Academies
CIREP	Institutional Committee for Ethical Review of Projects
D	Deliverable
DMP	Data Management Plan
EU	European Union
GDPR	General Data Protection Regulation
HE	Horizon Europe
IC	Informed Consent
iDEM	Innovative and Inclusive Democratic Spaces for Deliberation and Participation
IS	Information Sheet
M	Month
NLP	Natural Language Processing
PI	Principal Investigator
SHEA	Sexual Harassment, Exploitation and Abuse
T	Task
UNCRPD	United Nations Convention on the Rights of Persons with Disabilities
WMA	World Medical Association
WP	Work Package

1. Introduction

The iDEM project aims to remove the barriers that limit the participation of citizens who are marginalised from democratic processes due to the inherent difficulties associated with the language complexity in documents, debates, and discourses used and produced in democratic processes or settings. In addition to a theoretical investigation on the limitations of current marginalisation from deliberative processes specifically related to a lack of language skills, the project adopts a **user-centred approach** for designing more accessible and inclusive deliberative spaces. Thanks to the use of natural language processing technology iDEM aims to make information in participative democracy easier to produce, read, and understand, thus allowing a fairer engagement in democratic participation. Our project will develop use cases in Catalan, Spanish, and Italian languages, with a **diverse group of citizens** and deliberative processes. The project requires a **multidisciplinary approach and considerable user involvement** to contribute to the established objectives. The working user-centred methodology and the fact that new technologies will be developed for human use implies that ethical considerations must guide the research in the iDEM project whilst special care should be taken into account in order to weigh the risks and benefits of our proposed solution. Drawing from literature on ethical underpinnings in different areas of knowledge (e.g. engineering, health, social sciences) and from current and past projects which have shared goals with iDEM, we have developed the current document with the objective of informing and guiding the consortium in the adoption of an ethical framework for research within iDEM.

This document is produced in the context of WP6 and Task T6.1¹ and should be considered a living document that will be revisited throughout the project's life, modifying and adapting it, should it prove necessary.

The iDEM project carries out research with an intersectional perspective and, therefore, aims to analyse the dynamics of power, exclusion of vulnerable subjects or groups, based on gender identity, age, geographical origin and other factors that impact differently on the people with whom the research is conducted.

According to the intersectional feminist approach², it is necessary to rethink the way in which research is done, identifying evidence to dismantle prejudices and stereotypes with the aim of creating alternative narratives that challenge dominant thinking.

In this sense, iDEM will equip itself with an ethical protocol that will consider the intersectional lens throughout the entire project cycle. Given the purpose of the project and the target groups involved, particular attention will be paid to: the selection and composition of the participating groups, the acquisition of consent, their safeguarding, the disclosure and security of the data, and the information processed.

¹ Ethics Protocols and Monitoring.

² ActionAid, *Feminist Research Guidelines*, 2021 (p.6)
<https://actionaid.org/publications/2020/feminist-research-guidelines>

In the implementation of specific research activities and pilots, checklists will be created that answer a series of guiding questions on: who to involve, the methodology, how to mitigate any negative power dynamics, a risk matrix to mitigate Sexual Harassment, Exploitation and Abuse (SHEA) and safeguarding.

To cement this approach, consortium members will receive specific training³ from the other partners, recognizing that each partner brings unique knowledge, analysis and experience and that all participants in the project will learn and benefit from each other's expertise.

This report presents guidelines and protocols that will be followed throughout the iDEM Project HE. All of our work will be conducted following the EU Code of Conduct for Research Integrity. This documentation provides guidance and reference for all members of the consortium.

1.1. The European Framework

iDEM will follow the principles stated in the EU Code of Conduct for Research Integrity⁴, the Declaration of Helsinki (Christiane et al., 2000), and The Belmont Report, 2015 .

1.1.1. European Code of Conduct for Research Integrity

“The European Code of Conduct for Research Integrity serves the European research community as a framework for self-regulation across all scientific and scholarly disciplines and for all research settings”⁴. These principles and protocols cover aspects related but not limited to

- *Research integrity and reproducibility*: the research to be carried out in iDEM shall be reliable, that is, our findings should be reproducible. From a technological viewpoint, for example, it implies that data (and data partitions) and algorithms are open and evaluation procedures (e.g. metrics) are well documented. Moreover, the research produced in iDEM should be honest and truthful. iDEM is a publicly funded project, and as such, should honour the trust deposited in our project by the Horizon Europe research programme.
- *Training and mentoring of researchers*: iDEM senior researchers should strive to mentor more junior researchers and provide them with opportunities for professional development. Participation of junior researchers in the design, running, and reporting of experiments should be encouraged. Fair acknowledgement of researchers' contributions through the inclusion of their names as main authors in research publications is encouraged.

³ Training sessions are planned in Task T6.2 including a session on Introduction to SHEA & Safeguarding (date TBA).

⁴The European Code of Conduct for Research and Integrity, <https://allea.org/code-of-conduct/>

- *Precise and well-documented research procedures should be adopted.* iDEM will document the precise methods and procedures adopted and will make these available through deliverables, research papers, data, and software.
- *Research dissemination.* iDEM will seek to inform the scientific community on the projects' findings. iDEM partners should engage in dissemination events in venues of high standards to guarantee maximum impact. Research produced in iDEM should be findable in well-known on-line repositories (e.g. for scientific research Web of Science, Scopus). Moreover, iDEM should strive to produce collaborative research given the interdisciplinarity of the consortium, that is social sciences and technology should go hand in hand to inform society at large. iDEM partners should make the funding source explicit as indicated in the iDEM Handbook⁵
- *Recruitment and handling of subjects:* iDEM will follow strict ethical procedures to engage research participants avoiding coercion, it will also adapt information sheets and consent forms to the needs of the participants (e.g. easy to read format) and will seek alternative methods in case written information is not the best means of communication.
- *Privacy* shall be enforced meaning that no piece of information that allows identification of an individual participating in Use Cases or other research experiences shall be made public.
- *Risk/benefit analysis for participants:* iDEM subjects participating in Use Cases and Focus Groups will be informed of any risks of participation in iDEM activities as well as the expected benefits of the knowledge generated and the technology produced. iDEM aims at making both, knowledge generated and the technology developed, openly available in publications and as software libraries and datasets.

Special attention will be given to ethical aspects in the context of disability research. Our work will follow the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD) (Rasmussen & Lewis, 2007) adopted by the European Union and the best practices⁶, protocols, and experience from our user organisations (PIM⁷ and ANFFAS).

The work will also propose models in Easy Read that help consolidate the results of this task and that can be applicable in the field to ensure the ethical protocols are applied.

1.1.2. Belmont Report

The Belmont Report was ordered by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. "It is a statement of basic ethical principles

⁵[iDEM] D7.1 Project handbook, submitted M3 to the EC.

⁶ European Union and the best practices <https://webgate.ec.europa.eu/dyna/bp-portal/>

⁷ PIM, Código ético, 2021,

https://www.plenainclusion.org/wp-content/uploads/2021/03/codigo_etico_0.pdf

and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects.”

“This code became the prototype of many later codes intended to assure that research involving human subjects would be carried out in an ethical manner.”

It is based on three ethical principles: the principle of respect of persons, the principle of beneficence, and the principle of justice.

“Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.”

“Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence... Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximise possible benefits and minimise possible harms.”

“Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved."... whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.”

The principles stated in the Belmont report are intrinsically related to iDEM’s objectives. The research to be carried out with user groups will directly benefit these groups and other groups with similar barriers, regardless of nationality, social or economic status, disability, or gender. All our efforts are based on the protection of the subjects and their fully informed consent participation, making accessibility our main concern in terms of full comprehension of the information being communicated.

1.1.3. The Declaration of Helsinki

The Declaration of Helsinki, “The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.”

Although the declaration is mainly related to the health sciences, its ethical principles could be applied to our research. For example, iDEM use cases are “... based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in (medical) research should be provided appropriate access to participation in research.”

As iDEM research revolves around populations in vulnerable conditions, with cognitive disabilities, and poor accessibility. So we can relate to the declaration in the sense that “Research involving subjects who are physically or mentally incapable of giving consent... may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances ... informed consent from the legally authorised representative” should be sought.

In regard to personal data protection, the declaration clearly states: “It is the duty ...to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.” Through a strict protocol regarding data protection and processing, we seek to guarantee the confidentiality and anonymity of our user group.

With respect to dissemination of the findings of iDEM we will adopt the statement that “...Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations, and conflicts of interest should be declared in the publication.”

1.2. Technology and Ethics

Particular attention should be paid to issues related to the use of technology produced in iDEM, and although a special task⁸ in WP6 is dedicated to Natural Language Processing (NLP) and Ethics, we believe it is important to inform our stakeholders early through this document about the responsible use of the technology. In particular, we have drawn from the ACM Code of Ethics and Professional Conduct (Gotterbarn et al., 2018) several precepts that should be taken into account when developing research and deploying technology in Computer Science related fields:

⁸ [iDEM] T6.3 Ethics and NLP

Principle	Implications for iDEM
Contribute to society and to human well-being, acknowledging that all people are stakeholders in computing	Use the acquired skills to <u>benefit society as a whole</u> .
Avoid harm	The principle refers to <u>avoiding physical or mental injury, destruction or disclosure of private information, and damage to property or reputation or the environment</u> .
Be honest and trustworthy	Full disclosure of all system <u>capabilities, limitations, and potential problems</u> . Tasks that fall outside the capacities of the individual should be avoided.
Be fair and take action not to discriminate	Equality, tolerance, respect for others, and justice should prevail. Information technology should not cause or enhance existing inequalities. <u>Technology should be inclusive and accessible</u> . <u>Professionals should foster the participation of all people including underrepresented groups</u> .
Respect the work required to produce new ideas, inventions, creative works, and computing artefacts	Ideas, creation of tools, and resources, all should be credited to their creators and therefore publications should appropriately state correct and <u>proportionate authorship</u> .
Respect privacy	<u>Personal information</u> should only be used for legitimate ends. Collection of personal information should only be done if the <u>consent of the individuals</u> from whom said information is required is given. Personal information in records should be <u>anonymized</u> before sharing it to avoid re-identification. Records should be kept the minimum amount of time and disposed appropriately.
Honour confidentiality	Information such as business strategies, datasets, pre-published articles, patent applications should <u>not be disclosed outside the consortium</u> .

Note that all principles should be satisfied, for example it wouldn't be enough "not to harm" if the developed solution can not be benefited by the subjects who contributed to its development. This is particularly relevant for iDEM, since **we develop technology based on user-centred design, and we aim at making the solution available for our subjects and the society as a whole**.

2. Ethical Considerations for User Studies involving Vulnerable People

Considerable research has been published on the inclusion of vulnerable subjects as participants and informants in research projects. According to (Gordon, 2020a), the term vulnerability is at the centre of theoretical and practical application of ethics in research with human subjects. Although a fuzzy concept, it can usually be associated with the fact that risk of participation in research should be null or minimised, in other words humans must be protected from all harm. Several researchers (Smith, 2008), (González-Duarte et al., 2019), (Ketefian, 2015), (Gordon, 2020b) have classified types of vulnerable individuals where research participation is of concern including people who face *economic difficulties* (e.g. low income) who may decide to participate in research because of a monetary compensation, *low-literacy population* who might struggle understanding the implications of their research participation and therefore be unable to give valid consent; *subordinate subjects* who might feel forced to participate in research (e.g. coercion) because they are students, employees, subordinates, family or associated to the researcher or research funder; *people living with some maladie* who feel that participation may expose them (e.g. lack of confidentiality), *migrants and refugees* who may feel participation will put them in danger also in case of confidentiality breaches occur, *gender-diverse populations* who may feel the study would not treat them fairly or will be exposed to stereotypical profiling. iDEM is a project about inclusion and in order to achieve our objectives we aim at including a diverse group of people in order to make our findings as general as possible. Inclusion of vulnerable populations will be done with respect to the human rights of the persons and with special protection if needed. Some research (Feudtner & Brosco, 2011) elaborates the idea that people with disabilities do not require special protection beyond the protection and principles that apply to all subjects participating in research.

2.1. Overview of iDEM participants

As stated in the UNCRPD Preamble⁹ the concept of disabilities applies to those situations where people with impairments face barriers that hinder their full and effective participation in society on an equal basis with others. The social environment has a huge impact on the experience and extent of disability: structural barriers, attitudinal prejudices and lack of physical and communicative accessibility are true obstacles for participation and, thus, for real inclusion in the community.

iDEM methodology addresses specifically the linguistic barriers in deliberative processes, found by a diverse group of people: from non-native speakers to people with intellectual disabilities or low literacy skills due to cognitive impairments or ageing.

⁹ United Nations, Department of Economic and Social Affairs, Disability, <https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities/preamble.html>

3. Ethics Protocols: Adopting Universitat Pompeu Fabra Ethics Procedures

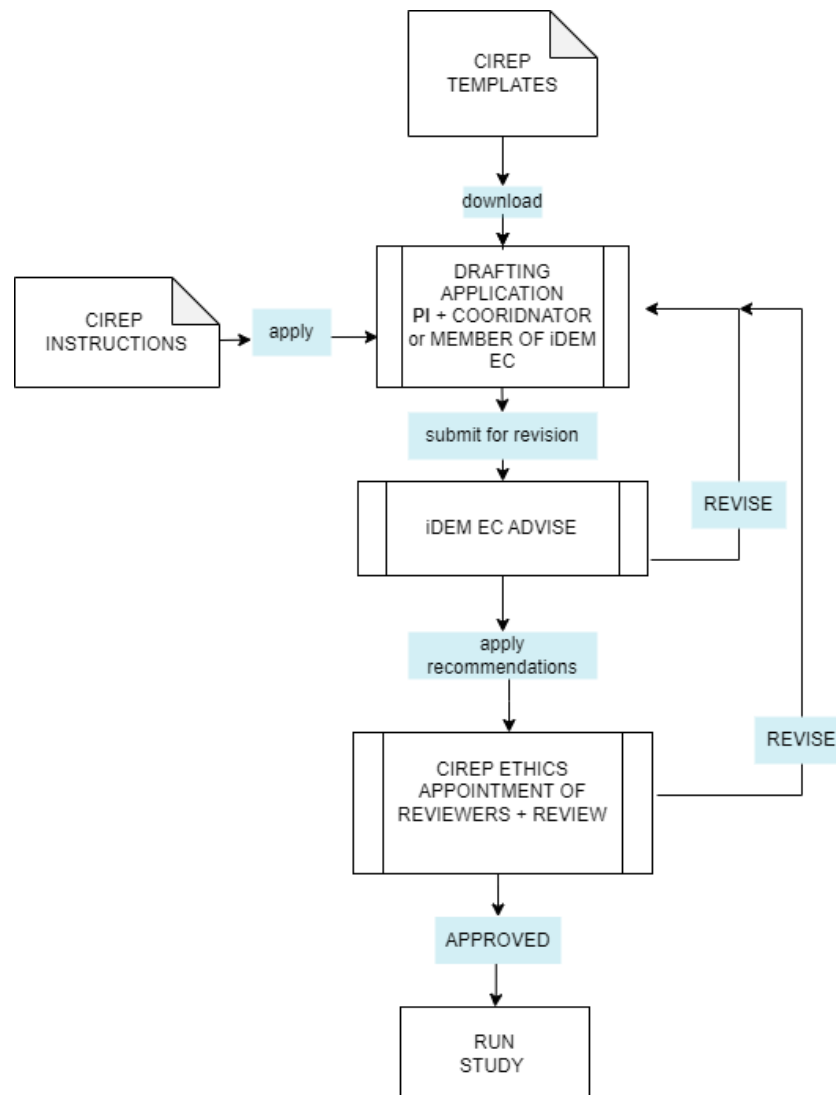
Faced with the demands for ethics approval in Horizon Europe projects and considering that most partners in the iDEM project, specially those in charge of carrying out work with users, do not have a dedicated research ethics board within their institutions, in spite of having well-established protocols for data collection and protection, we have requested the UPF CIREP office the possibility of assisting with ethical approval all partners in the project who may request so. Having obtained the authorisation to start the application process to the UPF Ethics Committee, we describe the standard application procedure to inform the consortium.

The application for ethics approval is an iterative procedure that will be supported by the Ethics Committee (See iDEM Handbook). The main responsible for the application procedure is the PI in charge of the research activity (e.g. interview, use case, focus group) involving human subjects. In order to fill in an application, the UPF CIREP office has provided documentation and Word template files which need to be instantiated for each application. The following forms need to be properly completed before application:

- A checklist form which helps determine if the experiment or activity needs to be submitted for ethics review.
- A protocol form which must be filled in with information about the project, objectives, participants and recruitment procedure, personal data processing, ethical considerations, and references. This protocol form is paired with an instructions document which explains how to complete the protocol.
- An informed consent form whose objective is to guarantee that human participants engage in the activity voluntarily and free from coercion, and that the participants fully understand how their data will be stored and processed. The form also contains an information sheet which explains the research activity. This form is also paired with an instructions document for reference.
- Finally, there is a data protection impact assessment form which provides information showing that the risks to participation have been considered and that appropriate measures have been taken to protect the participants.

The image below provides an overview of the flow of activities to obtain ethical approval¹⁰.

¹⁰ Universitat Pompeu Fabra example protocols form, forms adopted by iDEM can be found <https://www.upf.edu/web/cirep/review>



At the time of writing this report, several activities have been carried out to understand the ethical considerations we face in our project, as well as for preparing the first ethics application for iDEM. More concretely, we have started the ethical approval application for interviews and focus groups which are planned in WP4. The leaders of WP4 together with the Project Coordinator and the Project Manager have drafted an application which is in the process of revision. Early discussions have also been carried out with partners NEXUS, ANFASS, AAIT, BOO, PIM and IMPD to provide information on the ethical application process. Additionally, informative sessions have been scheduled for April and May on these matters with experts on the subject.

4. Managing Participation Consent

We have carried out an analysis of the literature in the area of informed consent (IC) for vulnerable people (Nandra et al., 2020), (Hadden et al., 2017), (Coleman et al., 2021), (Pietrzykowski & Śmiłowska, 2021) and also on the processes to verify whether the information has been understood to guarantee subjects' participation (Tamariz et al., 2012) Most of the reviewed literature focuses on the area of health. However several important considerations can be drawn from this literature.

- Informed consent should be always obtained from the participants, should this prove impossible, legal representative or tutor might act in their behalf, only and only if the participant agrees with the study
- Information about the research to be carried out should be provided in clear and thorough manner
- participation should be voluntary, no participant should feel coercion or any kind of constraint to participate
- participants should be the direct beneficiaries of the outcome of the research
- participant should suffer any kind of harm, before, during of after the study as a consequence of it

Easy to read accessible information sheets and consent forms are just one of the tools for informing research subjects and obtaining consent. Other interventions have been reported in the literature (Hadden et al., 2017), (Strickler & Haverkamp, 2023) including computer/human explanation, “teaching” methods, “conversational” modes, adoption of specific templates, reducing the text grade level, etc.

5. iDEM Partners Easy to Read Consent Forms

Our partner institutions working with vulnerable user groups have extensive experience when dealing with consent forms for focus groups and interviews. Easy to read, plain language, images and symbols have been used for different groups depending on their needs. Each partner has contributed their experiences so that iDEM can develop appropriate Consent Forms for our user population to be used in our use cases.

5.1. Experience of Institut Municipal De Persones Amb Discapacitat (IMPD)

IMPD, as a part of Barcelona City Council, is committed to adopting measures that improve people's trust towards institutions and their representatives, ensures institution accountability, integrity and access to information. With this objective, the City Council approved the Code of Ethics and Conduct¹¹, as means of a general regulatory provision, in compliance with the legal framework (Law 19/2014, on transparency, access to public information and good governance).

¹¹ <https://ajuntament.barcelona.cat/transparencia/ca/codi-conducta>

IMPD activity is based on the recognition of human diversity, the promotion of universal design and the implementation of reasonable accommodations if needed. Participation is core to IMPD's life, since the institution is committed to foster personal autonomy, independent living and freedom to make one's own choices. Therefore, the IMPD includes a diversity of communicative solutions to involve people with disabilities in a range of situations (easy-to-read language, plain-language, audio, Braille, large print, alternative information, written information, sign language). In the case of informed consent, the experience of the institution is limited to the use of plain language in ordinary clauses in written information related to data protection

5.2. Experience of Plena Inclusión Madrid (PIM)

The Plena Inclusión Ethical Code¹² highlights the dignity and value of the person with intellectual or developmental disabilities as one of the essential values of the federation, from which the principle of self-determination arises. The self-determination principle is the right of every person to be independent and make their own decisions.

In this sense, the organisation must have the necessary means so that each person, regardless of their ability, can express themselves, providing opportunities and support for them to freely express their complaints, desires, needs, aspirations, and beliefs.

For this reason, professionals and volunteers who work for Plena Inclusión must consult the person on any issue that affects them. When it is considered that it is not possible to carry out the consultation, in consensus with the family or guardians, and with the team of professionals, mechanisms will be explicitly provided to ensure that the decisions that affect them are made consistent with their interests, wishes, and needs.

In addition, each person must receive enough information to understand the available support systems and any other action that can improve their quality of life (objectives of the program, actions, possible risks, alternatives, and any other matter that is considered relevant). By doing this, each person will be able to give, or not, their informed consent.

With the aim of making the content of the consents understandable for people with intellectual or developmental disabilities, Plena Inclusión uses the Easy-to-Read method as the main tool to facilitate the understanding of the consents. To do this, Plena Inclusión makes adaptations for Easy-to-Read, and validates the content with a validation group of people with intellectual disabilities. The information that the consents include is: explanation of the study, time, form of participation, risks, and data protection.

In the case of personal data and confidential information, Plena Inclusión Madrid guarantees that the information is confidential and is only used for purposes exclusively related to the exercise of professional activities of the federation. The organisations of the federation have

¹²PIM, código ético, 2021, https://www.plenainclusion.org/sites/default/files/codigo_etico_0.pdf

explicit rules in their internal regulations and always inform the person or family in advance of the use that could be made of them (research, publications...).

5.3. Experience of Associazione Nazionale Famiglie Di Persone Con Disabilità Intellettiva Relazionale Anffas Onlus (ANFFAS)

Anffas Nazionale promotes the right of self-determination and self-representation of the person with intellectual or developmental disabilities as one of the essential values of the Association. The self-determination principle is the right of every person to be independent and make their own decisions.

In this sense, the organisation must have the necessary means so that each person, regardless of their ability, can be able to fully understand all the information and express themselves, providing opportunities and support for them to freely express their desires, needs and preferences.

For this reason, professionals and volunteers inside all Anffas Association (not only the national level) must consult the person on any issue that affects them. They will provide each person with information written in easy-to-read and a personalised support system and other actions that are proposed to achieve an improvement in their quality of life. In this way the person with a disability can express, in the best way for that said person, their consent.

When it is considered that it is not possible to let the person with a disability fully express their consent, the professionals will have to make a consultation with the family or guardians letting them understand that they have to take in consideration the desires, needs, and preferences of the person with a disability and not what they think the person itself need or want.

5.4. Experience of Fundación Cibervoluntarios (CIB)

CIB produces its results in accordance with the European (*The EU General Data Protection Regulation (GDPR)*, 2020) and Spanish¹³ GDPR. In this case, making sure that the participants who will take part in the activities are capable of taking their own decisions or have help regarding the informed consents. If the subjects are not capable of forming their own decisions or have difficulties, CIB will ask their legal tutors or guardians to give their own consent, making sure that the person who is going to participate in the activity has some knowledge in regards to the activities.

Before sending the participants the consent forms, CiB will send an information sheet, so they can read it, ask any questions and decide whether to participate or not. This helps our participants give their consent freely without feeling any kind of coercion. For iDEM, in

¹³ Spanish General Data Protection Regulation, <https://www.boe.es/eli/es/lo/2018/12/05/3/con>

particular, the information sheet and consent form are sent in the same document, which will facilitate that the consent form would not get lost, and that participants would be able to sign it prior to the start of the activity in question. Also, CIB doesn't have prior experience with easy to read language, so extra efforts are in please collaborating with PIM and the rest of the consortium to make sure that every informed consent that it is sent, has an easy-to-read version so all the participants would be able to fully understand the activities.

CIB guarantees that the collected information for analysis is going to be anonymized, secure and erased after 5 years of the project finalisation, as per GA. Protecting any kind of personal information from the participants guarantees that the information that it is collected complies with the Spanish and the EU GDPRs. In order to ensure the process, CIB will make sure that the participants would feel safe during the realisation of the activities by not collecting data that is not necessary for the project and giving a specific ID to each participant.

5.5. Experience of ActionAid Italy (AAIT)

According to the Code of Ethics approved by the International Federation, AAIT protects the confidentiality of the information and data of employees, business partners, volunteers, activists, supporters, recipients, suppliers, and companies collected due to or during their involvement in the activities. Each person in the exercise of his/her functions, will have to comply with standards and the law in effect.

In the case of personal data and confidential information, AAIT guarantees that the information in possession will be kept confidential and required to use it for purposes exclusively related to the exercise of professional activities.

AAIT uses a Consent Form both online and offline in which all the elements for privacy protection are inserted. The consent form contains information on project activities, the relevant legal provisions for data processing, the mechanisms, and contacts for requesting information and complaining. Any breach of the standards or provisions in this Code of Ethics will have to be promptly reported to the External Supervisory Body. Notifications must be made through the SEGNALAZIONI.NET platform (at <https://actionaid.segnalazioni.net/>), which guarantees absolute confidentiality and encryption of the reporter and the report, known exclusively to the recipient, the Supervisory Board.

The Consent Form is adapted from time to time based on the purposes and needs of the activity for which it is used. There is always a verification mechanism by the personal data protection officer, a staff resource. Depending on the collection method, data and information are stored under legal office custody or online. AAIT uses the ICT systems exclusively to perform its activities, in full compliance with laws governing the use and management of information systems and defined company procedures.

6. Ethics Committee (EC)

The responsibilities of the Ethics Committee are to monitor the ethical applications within the iDEM project and to ensure that the ethical principles are applied, monitoring the running of use cases and other interventions with human subjects.

The Ethics Committee is formed by 1 member from each partner institution. The Committee programmed meetings are monthly and daily informal communication happens as necessary. Due to the research being carried out in iDEM, we have a dedicated WP6 on Ethical Principles and Procedures, thus the committee receives input from all members of the iDEM Consortium.

We believe that the topic needs a multi-disciplinary approach with input from the following perspectives:

- Democracy
- Law
- Justice
- Technology
- User input

The Committee assures that

- The research is carried out at the highest level of integrity following the EU Code of Conduct for Research Integrity
- All members of the iDEM consortium receive appropriate training on the adopted ethical principles of the project
- All ethical principles are applied correctly
- Consent from participants in research activities is obtained and participants fully understand the procedures and implications
- Data is correctly handled, verified, and stored following the General Data Protection Regulation (GDPR)
- The developed technology is sensitive to social aspects avoiding bias and discrimination.

6.1. Composition

The membership to the committee is yearly renewed, consisting of one member for each partner institution. This information is stored in the membership database in the [iDEM] Google Drive. The Committee meets periodically to review procedures and monitor the correct application of these protocols.

For 2024-2025 period the Ethics Committee members are:

Name	Institution Acronym
Horacio Saggion	UPF
Almudena Rascón	PIM
Martin Gollegger	CAPITO
Lian Muñoz	CIB
Eleonora Severa	ANFAAS
Carlo Eugeni	UOL
Laura Trujillo	IMPD
Claudia Mazzanti	AAIT
John O'Flaherty	MAC
Eva Garcia Chueca	BOO
Volkan Sayman	NEXUS

6.2. Meetings

The Committee meetings started in February as soon as it was formed. Scheduled meetings are happening once a month, they have been scheduled until June through a poll system initiated by UPF WP6 Leader. Many other meetings happened in these first months working toward D6.1 Ethical Protocols, NEXUS ethical approval and CIREP welcome info session.

With this definition, iDEM's Code of Conduct for use of AI is as follows:

1. Prioritise Explainability and Transparency:

- **AI Models:** Clearly explain the decision-making process behind any AI-powered language simplification or bias detection tools. This is vital for building trust with users, especially those from marginalised groups. The AI Act mandates explainability for high-risk systems, which could apply to iDEM's tools if they impact decision-making processes within democratic participation.
- **Data Usage:** Transparently communicate how user data is collected, stored, and used to train AI models. Ensure alignment with the GDPR and the AI Act's data governance principles.
- **Limitations:** Acknowledge the inherent limitations of AI-based language tools. Emphasise that AI is an assistive technology, not a replacement for human judgement within democratic processes

2. Address Algorithmic Bias and Fairness:

- **Diverse Datasets:** Train AI models on diverse and representative datasets to mitigate bias against specific language styles, dialects, or language skill levels. This is essential for promoting inclusivity and fairness in iDEM's tools.
- **Bias Detection:** Develop robust bias detection mechanisms within iDEM's AI systems to flag and address potentially discriminatory or harmful outputs. This aligns with the AI Act's focus on mitigating the risks of biased AI.
- **Human Oversight:** Establish clear human oversight processes to review and correct AI-generated suggestions or adaptations. This safeguards against automated decisions that perpetuate marginalisation.

3. Emphasize User-Centric Design:

- **Accessibility:** Design the iDEM interface with accessibility in mind, catering to the diverse needs of users with varying language abilities. Consider multiple input modalities (text, voice, visuals) and customizable output formats.
- **Iterative Development:** Engage users from marginalised communities throughout the design process. Seek their feedback on iDEM's tools, and iteratively improve them to ensure they are genuinely helpful and empowering.

- Collaboration: Partner with organisations and advocates specialising in supporting marginalised communities to ensure iDEM's tools align with their specific needs and challenges.

4.Foster Ethical AI Practices:

- Fundamental Rights: Explicitly embed respect for fundamental rights, like non-discrimination, within iDEM's design principles. This is essential for building trust and ensuring the project aligns with the AI Act's core values.
- Impact Assessment: Conduct regular ethical impact assessments to evaluate the potential unintended consequences of iDEM's technology. Proactively address any concerns with mitigation strategies.
- Code of Conduct: Constantly review and update this project-specific code of conduct regarding safe, responsible, and ethical use of AI. This demonstrates iDEM's commitment to transparency and accountability.

5.Navigate the Regulatory Landscape:

- Proactive Compliance: Stay ahead of the curve by actively monitoring developments in the AI Act and related regulations. Ensure iDEM's technology, particularly any AI components, are designed with compliance in mind.
- Data Protection: Implement robust data protection measures in line with the GDPR. Obtain clear informed consent from users before collecting any personal data.
- Risk Assessment: As iDEM develops, conduct ongoing risk assessments to identify and mitigate potential harms associated with its AI tools. This is a key requirement for high-risk systems under the AI Act.

9. Conclusion and Further Work

This deliverable, in its first version, describes the ethical underpinnings which will guide the research to be carried out in iDEM. Drawing from key principles put forward by the Belmont report, the Declaration of Helsinki, and two Codes of Conduct together with a broad literature on participation of vulnerable subjects in research, we have created this initial document. Acknowledging the fact that research in iDEM should be screened for ethical

approval we have put forward an ethical procedure application to be followed by Consortium members in charge of developing research with human participants. This procedure for preparation of ethics applications is advised by the Ethics Committee which function and form are described in our Project Handbook. At the time of writing the first application has already been submitted for approval.

In future versions of this deliverable we shall describe the ethics applications submitted together with any advice and lessons learned by applying the ethics protocols. The information will be used to appropriately update our protocols in case of need. Moreover, aspects related to the new Artificial Intelligence Act adopted by the European Union will have a special focus in the second version of this deliverable.

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Annex 1

Sample of Easy to Read Consent Form¹⁶ template for research

Identify your study and the people involved

Study Title	Name and contact details
Principal Investigator (Person in charge of this study)	<i>Name, degree, title, department Phone and e-mail</i>
Study Coordinator	<i>Name, Phone and email</i>
Study Contact Information	<i>Phone and/or email</i>

1. Why have I been given this document?

[Include the following statement as written. Do not edit or add to it.]

To see if you are interested in taking part in a research study. A research study is a planned project done to learn more about a topic.

2. Do I need to take part in this research study?

[Include the following statement as written. Do not edit or add to it.]

No. Taking part in research is voluntary. If you don't want to take part there will be no penalty and you will not lose your current benefits.

The Principal Investigator, or another member of the study team, will explain the study to you. Please ask questions.

Take your time deciding if you want to be in this study. You can talk with your health care team, your family, and friends before deciding.

....

17. Can I be removed from the study by the Principal Investigator?

[Include the following statement as written. Do not edit or add to it.]

¹⁶ Example questions of [Easy to Read Consent form](#) template from UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

Yes. The Principal Investigator may stop you from taking part in this study at any time. This could happen without your permission. It could be because it is in your best interest, if you did not follow the study rules, or the study has been stopped.

18. What are my rights if I take part in this study?

[Include the following statement as written. Do not edit or add to it.]

You may choose to take part or not to take part in this study. It's your choice. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

19. Who can answer my questions about this study?

[Include the following statement as written. See the Companion Document for guidance about listing additional informational sources.]

You can contact the study team with any questions, concerns, or complaints you have about this study. The contact information is on the first page of this form.

UCSF has an office that can answer questions about your rights as a research participant. This office is called the Institutional Review Board (IRB). The IRB is available to talk about any problems or concerns you have about the study. The UCSF IRB's phone number is 415-476-1814.

19.1 Where can I get more information about this study?**20. Consent**

You will be given a copy of this form to keep.