

ABLE TO INCLUDE
(GA N° 621055)

**Ethics Considerations on Software Development
for IDD Users**

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1 GUIDING FRAMEWORKS

Research frameworks should not differ from those for persons without disabilities (1; 2), but researchers should still recognize adults with ID as less privileged and vulnerable, thereby necessitating rigorous, ethical research, especially for those living independently, in institutional care, and in countries where rights are tenuous (1; 3). This is why we believe that in some way, there should be increased protections for research with adults with ID (4), keeping in mind that a strong emphasis on protections may exclude adults with ID from research and thwart their ability to benefit (5; 6; 7; 8; 9; 10).

We believe in the the benefits of a human rights framework that balances needs and respect for dignity (3), where adults with ID have the opportunity to participate and make choices, but simultaneously, where they might need assistance making decisions and need to be protected from harm.

The guiding frameworks used to underpin this document of good practice are:

- FEAPS
- Document from ECRS: Economic and Social Research Council
- Recent literature research on ethical discussions in research with IDD

2 GOOD PRACTICE

2.1 RECRUITING

Before recruiting potential users, several topics needed to be taken into account. First, a decision needed to be made on who to include or exclude as participants. The Able To Include consortium therefore created a document that defined the target group of the research project (annex 1). Both persons with IDD with and without legal guardians can participate (11; 9), and neither the presence of a disability nor the absence of capacity to consent should exclude an individual from participating in research (5; 12; 13; 14; 15; 8; 16; 3; 17). All their views provide opportunities to influence research (18). Recruitment of the users will thus be directed from the target group definition, but will not be limited by it. All users who show interest in the Able To Include project are welcome to participate, although it should be said that it could be that some persons with IDD could be prohibited from participation to the research project to protect them from harm (19; 20). This decision for participation should always be made with a focus on self-determination, dignity, and the right to autonomy for persons with IDD, but should also integrate protective measures when necessary.

There are several ways to recruit persons with IDD for research.

Most of the time, persons with IDD were recruited through supporters, keeping in mind that supporters may screen adults with ID for inclusion or exclusion (21). On the other hand, working directly with those who are known and trusted by adults with ID, including supporters, could help the persons with IDD to make a well-informed decision (11; 20; 21). We thus emphasized the voluntary nature of participation when informing these supporters (2), keeping in mind that some screening from supporters will be inevitable. We also encouraged persons with IDD to consult someone close to them non-related to the research, to discuss their participation, especially when researchers have a preexisting relationship with participants (14). In several cases, the persons with IDD turned to their parents for advice.

As most of the participants will be offered to use a tablet/smartphone with tools that should facilitate the use of digital media, this could be a strong incentive. This should not be the only motivation to participate to the research, this is why we will not stress this when asking for participants. There will be no monetary reimbursement to avoid incorrect motivation.



Following these general guidelines, each partner had its own way to recruit users, as they are situated in different countries, and are different organizations with its own characteristics.

Thomas More:

Thomas More needed to do the recruitment through supporters of persons with IDD, as Thomas More has no direct contacts with persons with IDD. Thomas More has informed professionals from different institutions in Flanders about the pilot projects, providing them with all the necessary information so that they could in their turn, inform their users. This allowed them to discuss potential participation to the research together with their users and to make a well-informed decision to join the pilots with their users.

Prodis Foundation:

The Prodis Foundation, at its headquarters, hosts various training programs so that the recruitment of the participants was a little easier. Professionals working directly with them in different programs studied very thoroughly what people would be wise to recruit for the project, taking into account their capabilities and their needs.

The professionals were thoroughly informed about the project so they could give all the necessary information to the guardians, parents and to the people with IDD that were going to participate in the pilots and in the whole project.

2.2 INFORMED CONSENT

All different pilot partners should receive approval from their local ethics committee when enrolling in the research process.

2.2.1 Briefing procedure

Before they give consent, potential participants should be properly briefed about the Able To include project, and about the pilot study.

They will be informed about:

- What they will be asked to do
- How long will it take
- Who will be conducting the study, whether anyone else will be present
- Whether they will be audio or video recorded and what exactly will be recorded
- A reasonable estimation of whether it will be boring, difficult, stressful etc.
- What they should do if they wish to withdraw, with information that this is their right and won't have negative consequences, particularly on their reimbursement
- Who will have access to their data, where and how long it will be stored, with appropriate information about anonymity and confidentiality
- How will the results be disseminated

To promote understanding of the research concept, several actions are undertaken. All information about the study (not only during recruitment, but at all stages of the study) will be provided in formats suitable for the particular participants. Individualized approaches might include presenting information in relationship to familiar situations and experiences and using simple, jargon-free language, symbols, pictograms, concrete visual aids, and multiformat practical demonstrations, repeating information, providing information in person verbally with nonverbal communication



signals, and allowing participants increased time to make decisions (22; 11; 23; 13; 1; 24; 25; 2; 26; 14).

Researchers will choose the locations where they will brief participants wisely, altering environmental stressors (13; 2) such as avoiding crowded rooms, or rooms that provide too much diversion.

The information about the research directed at the persons with IDD will be shortened to essential points necessary for an informed decision, including confidentiality and risks (5; 23; 24; 25; 14; 8; 16). All the researchers working on the pilots have previous relevant experience in working with persons with IDD, and implementing and developing tailored strategies (14; 27; 28).

2.2.2 Getting consent

The presence of IDD indicates neither the ability nor lack thereof to provide consent (7; 14). Moreover, a lack of capacity does not necessarily mean that they lack capacity to make other decisions (26), and there is no association between total consent comprehension and the ability to communicate a decision. Persons with IDD without capacity can still decline participation and evidence a decision (29). For these reasons, we consider capacity to consent along a continuum so that even those who partially understand the risks and benefits can participate to the Able To Include project. Consent can be viewed as an ongoing, emergent process with participants' understanding and agreement unfolding throughout the research (30; 23; 13; 25; 31; 3; 17; 28) We assume persons with IDD capable of providing consent unless established otherwise by formal assessment or legal determination (11; 13; 29).

A lot of potential participants have legal guardians, so it must be ensured that participants have understood and given voluntary consent (5; 6). We choose for a negotiated approach to consent, inclusive of others present in the lives of adults with ID, where autonomy is considered an expression of connectedness to others that guide and help with decision-making (2; 32). Participants can use natural supports by bringing a family member, friend, or advocate to consent meetings to help review information, promote understanding, and make a decision (31; 2; 14; 3; 32). These negotiated consent processes may result in proxy decision-making but it will also help researchers balance protecting those vulnerable to coercion or those who are included without consent with including them (23; 3).

Once a participant had been briefed, he was given an appropriate time to consider the situation or to discuss it with a supporter, as mentioned above. Afterwards, he or she was asked to give their consent.

Thomas More: They could either sign an tailored form (see Annex), or if not appropriate or within his or her abilities, supporters and/or legal guardians signed for them after receiving verbal consent from the potential participant. Alternative consents are provided for legal guardians and supporters as well.

2.3 DURING THE PILOTS

As mentioned before, all the pilot partners will carry out the testing in different circumstances. Mentioned below are some guidelines that we all agree on, and that can be adapted to each specific situation.

2.3.1 Testing procedures

During the study, participants will be treated with respect and common sense. They should not be asked to undertake activities for unreasonable periods without comfort and refreshment breaks, in conditions that are uncomfortable etc. They will not be asked to repeatedly fulfill the same task, so that they don't become frustrated with the testing process.



Participants will be given access to appropriate hardware and software and support in using that equipment so that they can complete the study in an appropriate and comfortable manner. They will not be asked to test- non working technical tools, even though this might result in less feedback.

As deadlines are installed, and arrangements are made with several partners, everyone should put effort into meeting these deadlines.

2.3.2 Withdrawals or new participants

Participants are free to withdraw from the project without any consequence. They will be informed about this during the briefing. On the other hand, as long as it's manageable for researchers and supporters, new participants can be added to join the pilot testing. There should not be too far over 50 participants per pilot-partner, as this would not be manageable with current resources.

Not achieving the 50 user threshold may not lead to forcing persons with IDD to participate. The Able To Include consortium believes it's better to invest in those agreeing to participate, and to ensure quality over quantity when engaging in the testing process. As this will lead to motivated participants, enthusiasm could spread resulting in more potential participants.

2.3.3 Guaranteeing prolonged engagement

As testing happens over a period of several months, it could be that participants will withdraw, for different reasons. Researchers will put effort into guaranteeing prolonged engagement. We believe it's most important to keep the participants motivated throughout the testing process. Building relationships with participants could also help prolonged engagement.

All the partners have engaged professionals working with the participants to organize testing moments, together or without the researchers. Researchers have informed these researchers on how to conduct these moments, and provide support when necessary. There is a direct communication with the researcher and professionals. To facilitate collaboration between all parties, participants can bring someone to support them (21) to meetings. Researchers will also take the time to get to know participants as this promotes respectful, mutually beneficial relationships between researchers and those who they study (25; 33; 21).

Establishing a relationship with the participants also holds some consequences. Researchers need to live up to the trust that is placed in them (1), which is why Able To Include researchers will clearly establish their role and identity as researcher (34; 16; 6; 25; 21). This could include asking participants to explain their expectations for the relationship, including expectations for continued friendship, so that there can be a clear negotiation of the relationship (21). Able To include researchers will discuss this relationship issue with their participants when first meeting them, clearly defining their role.

At last, testing moments will be organized in a way that will keep participants motivated: it will be tailored to their interests and needs. Examples are: organizing challenges between participants, ...

2.4 AFTER THE PILOTS

2.4.1 Debriefing

When the study is complete, participants will be given an explanation of the rationale for the study, how their participation fitted into the complete study and how the data will be analyzed.

The debriefing will be an interesting and educational experience for the participant and their supporters and they should leave the study feeling their participation was worthwhile. The debriefing also provides an opportunity for researchers to end the relationship between researchers and participants. This will be done at a composed pace in which participants do not feel exploited (21).



Participants and their supporters will be given adequate opportunity to ask questions and where possible, and they will be able to continue using the technical tools.

2.5 TREATMENT OF DATA

Several actions will be taken to ensure the confidentiality and anonymity of participants' data.

Treatment of data is governed not only by professional ethics, but by the data protection legislation and directives of the partner countries and the EU.

In all computer files, participants will be referred to by a code that cannot identify them. For example, codes including the participants' initials should be avoided. One researcher will retain the mapping from codes to participant names, but this information should not be stored on a computer and should be kept in a secure place.

All computer files should be stored only on secure machines. Particular care should be taken on security issues if files are transferred between partners for analysis. This should be undertaken using secure means.

Audio and video files should not be shown beyond the immediate research team without the explicit permission of the participants. For example, if an excerpt from a videoed session is to be used at a public presentation such as a conference, explicit permission should be obtained from the participant/s involved.

When data are reported in project deliverables or in public documents, attention must be paid to the anonymity of data. Data should mainly be reported in an aggregate manner, so that information from individual participants cannot be identified. If individual information is included, for example, comments from individual participants, it should be reported in ways that does not identify or embarrass the individual.



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